

No. 89-243-CFX
Status: GRANTED

Title: Eli Lilly and Company, Petitioner
v.
Medtronic, Inc.

Docketed:
August 11, 1989

Court: United States Court of Appeals for
the Federal Circuit

Counsel for petitioner: Malloy, Timothy J.

Counsel for respondent: Johnson, Philip S., Kauffman, George,
Lynch, John F.

Entry	Date	Note	Proceedings and Orders
2	Jul 21 1989	D	Application (A89-62) to recall and stay pending the timely filing and disposition of a petition for a writ of certiorari, submitted to Justice White.
4	Jul 21 1989		Lodging received. (Lodging filed with application for stay).
3	Jul 24 1989		Application (A89-62) denied by Justice White.
1	Aug 11 1989	G	Petition for writ of certiorari filed.
5	Sep 1 1989	G	Motion of Proctor and Gamble for leave to file a brief as amicus curiae filed.
6	Sep 11 1989	G	Motion of Senator Orrin G. Hatch, et al. for leave to file a brief as amici curiae filed.
7	Sep 11 1989		Brief of respondent Medtronic, Inc. in opposition filed.
8	Sep 11 1989	G	Motion of American Sterilizer Company for leave to file a brief as amicus curiae filed.
9	Sep 11 1989	G	Motion of Intellectual Property Owners, Inc. for leave to file a brief as amicus curiae filed.
10	Sep 11 1989	G	Motion of Zimmer, Inc., et al. for leave to file a brief as amici curiae filed.
11	Sep 11 1989	G	Motion of Pfizer Hospital Products Group, Inc., et al. for leave to file a brief as amici curiae filed.
12	Sep 13 1989		DISTRIBUTED. October 6, 1989
13	Sep 19 1989	X	Reply brief of petitioner Eli Lilly and Co. filed.
14	Sep 30 1989		Opposition of respondent to motion of Intellectual Property Owners, Inc. for leave to file a brief as amicus curiae filed.
15	Sep 30 1989		Opposition of respondent to motion of Senator Orrin G. Hatch, et al. for leave to file a brief as amici curiae filed.
16	Oct 3 1989		Opposition of respondent to motion of Pfizer Hospital Products, et al. for leave to file a brief as amici curiae filed.
17	Oct 10 1989		Motion of Proctor and Gamble for leave to file a brief as amicus curiae GRANTED. Justice O'Connor OUT.
18	Oct 10 1989		Motion of Senator Orrin G. Hatch, et al. for leave to file a brief as amici curiae GRANTED. Justice O'Connor OUT.
19	Oct 10 1989		Motion of American Sterilizer Company for leave to file a brief as amicus curiae GRANTED. Justice O'Connor OUT.
20	Oct 10 1989		Motion of Intellectual Property Owners, Inc. for leave to file a brief as amicus curiae GRANTED. Justice O'Connor OUT.

Entry	Date	Note	Proceedings and Orders
21	Oct 10 1989		Motion of Zimmer, Inc., et al. for leave to file a brief as amici curiae GRANTED. Justice O'Connor OUT.
22	Oct 10 1989		Motion of Pfizer Hospital Products Group, Inc., et al. for leave to file a brief as amici curiae GRANTED. Justice O'Connor OUT.
23	Oct 10 1989		Petition GRANTED. Justice O'Connor OUT. *****
24	Oct 20 1989	C	Application (A89-62) refiled and submitted to The Chief Justice.
27	Oct 20 1989		Record filed.
25	Oct 23 1989	*	Certified copy of original record received.
26	Oct 23 1989		Application (A89-62) referred to the Court by the Chief Justice.
29	Oct 24 1989		(A89-62) OCTOBER 27, 1989 CONFERENCE
30	Oct 30 1989		(A89-62) Response to the application requested by the Court, due October 31, 1989.
31	Oct 31 1989		(A89-62) NOVEMBER 3, 1989 CONFERENCE.
32	Nov 2 1989		(A89-62) Opposition of respondent to petitioner's reapplication filed.
33	Nov 6 1989		(A89-62) Reply of petitioner in support of reapplication filed.
34	Nov 6 1989		Application (A89-62) denied by the Court.
41	Nov 21 1989		(A89-62) Justice O'Connor OUT.
35	Nov 22 1989		Brief amicus curiae of Procter & Gamble Company filed.
36	Nov 22 1989		Brief of petitioner Eli Lilly and Co. filed.
37	Nov 22 1989		Brief amici curiae of Zimmer, Inc., et al. filed.
38	Nov 22 1989		Brief amicus curiae of Industrial Biotechnology filed.
40	Nov 22 1989		Brief amicus curiae of Intellectual Property Owners, Inc. filed.
39	Nov 24 1989		Joint appendix filed.
42	Nov 24 1989		Brief amici curiae of Pfizer Hospital Products, et al. filed.
43	Nov 24 1989	G	Record filed.
44	Dec 11 1989		Certified copy of original record, 2 boxes, received.
46	Dec 18 1989		Motion of Neuromedical Technologies, Inc. for leave to file a brief as amici curiae filed.
48	Dec 21 1989		Motion of Neuromedical Technologies, Inc. for leave to file a brief as amici curiae GRANTED. Justice O'Connor OUT.
47	Dec 27 1989		Order extending time to file response to petition until January 5, 1990.
49	Jan 2 1990		Brief amicus curiae of Dr. Gust H. Bardy filed.
50	Jan 2 1990		Brief amicus curiae of Ventritex, Inc. filed.
51	Jan 3 1990		Brief amicus curiae of Paralyzed Veterans of America filed.
52	Jan 5 1990		Brief amicus curiae of Dr. Denton Cooley filed.
53	Jan 5 1990		Brief amicus curiae of Teletronics, Inc. filed.
54	Jan 5 1990		Brief amici curiae of University of Minnesota, et al. filed.
55	Jan 5 1990		Brief amicus curiae of Cook Goup Incorporated filed.
56	Jan 5 1990		Brief amicus curiae of Carbon Implants Incorporated filed.
			Brief amici curiae of Pennsylvania, et al. filed.
			Brief of respondent Medtronic, Inc. filed.

Entry	Date	Note	Proceedings and Orders
57	Jan 5 1990		Brief amicus curiae of American Assn. of Retired Persons filed.
58	Jan 5 1990		SET FOR ARGUMENT MONDAY, FEBRUARY 26, 1990. (4TH CASE)
61	Jan 5 1990		Brief amicus curiae of Intermedics, Inc. filed.
59	Jan 17 1990		CIRCULATED.
60	Feb 2 1990	X	Reply brief of petitioner Eli Lilly and Co. filed.
62	Feb 26 1990		ARGUED.

AUG 11 1989

JOSEPH F. SPANIOLO, JR.
CLERK

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

TIMOTHY J. MALLOY

Counsel of Record

LAWRENCE M. JARVIS

GREGORY J. VOGLER

MCANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

The petitioner Eli Lilly and Company ("Lilly") respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.¹ The question presented is purely a legal one. Because the Court of Appeals' decision is so clearly erroneous, this case is appropriate for summary reversal pursuant to Rule 23.1 of the Rules of this Court.

¹ Pursuant to Rule 28.1 of the Rules of this Court, Lilly states that it has no publicly owned parents, subsidiaries, or affiliates.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 872 F.2d 402, and is reprinted in the appendix ("Pet. App.") hereto, page 1a. The Court of Appeals denied a timely petition for panel rehearing on May 31, 1989 (Pet. App. 8a), and issued its judgment as a mandate on June 8, 1989 (Pet. App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing in banc on July 18, 1989 (Pet. App. 9a).²

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania rejecting 35 U.S.C. § 271(e)(1) as a defense to patent infringement for medical devices is reported at 5 U.S.P.Q. 2d 1760 (Pet. App. 15a). The district court issued a memorandum decision, 7 U.S.P.Q. 2d 1439, supporting the issuance of a permanent injunction against respondent (Pet. App. 21a). The district court further issued a memorandum decision, 7 U.S.P.Q. 2d 1447, directing that judgment be entered in favor of Lilly (Pet. App. 41a).

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the Court of Appeals was invoked pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1).

The decision of the Court of Appeals was entered on March 29, 1989 (Pet. App. 1a). A timely petition for rehearing was denied on May 31, 1989 (Pet. App. 8a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

35 U.S.C. § 271(e)(1) provides as follows:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act

² This Court (White, Justice) denied Lilly's application to stay the mandate of the Court of Appeals on July 24, 1989. See Docket No. A-62.

and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The full text of 35 U.S.C. § 271(e) is set forth in petitioner's appendix, pp. 62a-63a.

STATEMENT OF THE CASE

Lilly holds the rights to the two patents in suit, which cover an automatic implantable cardioverter defibrillator and associated electrical leads.³ This medical device treats life-threatening heart arrhythmias in patients who are at high risk of sudden cardiac arrest. The defibrillator dramatically improves the prognosis for persons who have suffered an episode of sudden cardiac arrest: patients with the device have a one-year survival rate of 95-98 percent, compared to 30-60 percent for those without it (Pet. App. 23a-24a).

Pursuant to 28 U.S.C. § 1338(a), Intec Systems, Inc. ("Intec") brought this suit in 1983 in the United States District Court for

³ The automatic implantable cardioverter system functions like a miniaturized emergency room which may be implanted in the body of the patient. It automatically monitors the heart and shocks the heart back to its normal rhythm when conditions of ventricular tachycardia (abnormally fast heartbeat) or ventricular fibrillation (fluttering of the heart muscles) occur.

The inventor and his initial investor, Intec Systems, Inc., a small Pittsburgh-based company, toiled for ten years from the time of the invention until the first human implant in 1980 of a commercial embodiment of the patented invention. It took another five years, until 1985, before the Food and Drug Administration approved the patented product for commercial use. In 1985, Lilly paid the developers of the inventions in suit in excess of \$60 million plus additional royalties for the exclusive rights to the patented inventions and other assets. Lilly immediately sublicensed its exclusive implantable cardioverter defibrillator patent rights to its wholly owned subsidiary, Cardiac Pacemakers, Inc. ("CPI"). CPI, but not Lilly, makes, uses, and sells automatic implantable cardioverter defibrillators.

the Eastern District of Pennsylvania against respondent Medtronic, Inc. ("Medtronic"). After purchasing certain of Intec's assets in 1985, Lilly was substituted for Intec as the plaintiff. The complaint alleged that Medtronic's development and marketing of its devices infringed the two patents. Plaintiff sought damages and injunctive relief.

In 1987, Medtronic raised a pretrial defense that it made and sold the infringing devices for the purpose of obtaining FDA marketing approval, and that 35 U.S.C. § 271(e)(1) immunized this activity.⁴ Section 271(e)(1) was enacted in 1984 and provided then as follows:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.⁵

The district court ruled that this section is limited to drugs and does not provide an exemption for infringing medical devices (Pet. App. 15a). The court reasoned that the statute "clearly speaks" solely in terms of drugs, and the legislative history "evinces the narrow purpose of Congress" to establish a limited exemption for the testing of generic drugs (Pet. App. 18a-19a). "Nowhere," the district court concluded, "is there any indication that Congress had a broader intention to include medical devices within the coverage of § 271(e)(1)" (*id.*).

⁴ Although this lawsuit was initiated in 1983, Medtronic did not raise the Section 271(e)(1) defense until 1987, after Medtronic lost the reexamination proceedings on the patents in suit before the United States Patent and Trademark Office, and nearly two and one-half years after enactment of Section 271(e)(1).

⁵ Section 271(e)(1) was amended in 1988 to include certain animal products. Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988). The Court of Appeals stated that the amendment did not affect its analysis (Pet. App. 4a). As shown below, however, the amendment confirms the correctness of the district court's and Lilly's interpretation of the statute.

Following a jury trial, the court granted a directed verdict in Lilly's favor with respect to infringement of one patent, and the jury returned a verdict in Lilly's favor with respect to infringement of the other patent, including a jury finding that Medtronic willfully infringed both patents in suit (Pet. App. 22a, 35a). The district court further determined that the patents were valid and enforceable, and it directed that judgment be entered in Lilly's favor in the amount of \$26,666,000 (Pet. App. 41a-42a, 55a). The court also entered a permanent injunction against Medtronic's infringement of the Lilly patents (Pet. App. 22a, 40a).

On appeal from the injunction pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1), the Court of Appeals reversed and remanded (Pet. App. 1a). The Court of Appeals concluded that Lilly and Medtronic had "put forth equally plausible interpretations of section 271(e)(1)," and it found both the language and legislative history of the statute to be ambiguous (Pet. App. 5a). The court ruled in Medtronic's favor, however, on the basis of an argument that it developed *sua sponte*.

In the Court of Appeals' view, Section 271(e)(1) should be interpreted by reference not to its language, but to Congress' intent to overrule a prior case involving infringement of a drug patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). The Court of Appeals claimed there was a congressional intent to overrule *Bolar* "in all of its ramifications" (Pet. App. 7a), i.e., with respect to numerous other products, including medical devices, food additives, and color additives.

Lilly timely sought rehearing and rehearing in banc. Because of the importance of the court's holding, numerous *amicus* briefs were submitted by manufacturers of medical devices and other FDA-regulated products, as well as by Senator Hatch, the principal author of Section 271(e)(1), and Representative Moorhead, a floor manager for the legislation, supporting Lilly's petition. The Panel, however, denied rehearing without opinion on May 31, 1989 (Pet. App. 8a).

On July 18, 1989, the Court of Appeals declined Lilly's suggestion for rehearing in banc (Pet. App. 9a). Judge Newman dissented on the grounds of the "exceptional importance" of the

case and "the weight of the panel's error" in departing from the clear statutory language (Pet. App. 10a, 13a). Judge Newman indicated that the Panel erroneously "held that the statutory words 'drugs and veterinary biological products' include medical devices." (Pet. App. 10a). Judge Newman further stated:

The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and *amici* on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs. Congress would be expected to consider the public and private economic and policy aspects of these complex industries. I cannot imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the courts to amend statutes under the guise of 'statutory interpretation'").

(Pet. App. 12a-13a) (footnote omitted).

REASONS FOR GRANTING THE WRIT

I. Certiorari Is Necessary to Correct the Court of Appeals' Clear Error on a Matter of National Importance

This is not an ordinary patent case. It involves the construction of a federal statute that will have, unless reversed, a significant negative impact on investment in health-care research and development and on the pace of innovation in lifesaving medical devices. Congress enacted Section 271(e)(1) as part of the most substantial overhaul of the federal food and drug laws in more than twenty years. This statute does not raise any issue within the particular competence of the Federal Circuit. To the contrary, it requires only traditional tools of statutory construction. It also involves an understanding of FDA regulatory processes that is not a routine part of that court's jurisprudence. Moreover, because all appeals concerning patent matters and Section 271(e)(1) are within the exclusive appellate jurisdiction

of the Federal Circuit pursuant to 28 U.S.C. § 1295, the structure of the medical device industry will be changed irretrievably in a manner never anticipated by Congress if this Court does not grant certiorari now.

This Court should grant certiorari for several persuasive reasons discussed in detail below. As Judge Newman stated in her dissent from the denial of the suggestion for rehearing in banc, this case raises a federal statutory issue of "exceptional importance" (Pet. App. 10a, 13a). The decision below ignores the plain language of Section 271(e)(1), notwithstanding the "clarity of [its] words" (*id.* at 13a). By doing so, the Court of Appeals "has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest" (*id.* at 12a).

This Court has granted certiorari in cases decided by the Federal Circuit when important statutory issues were raised, and Congress clearly intended that such access to this Court would be available. *See, e.g., Cornelius v. Nutt*, 472 U.S. 648, 657 (1985); H.R. Rep. No. 312, 97th Cong., 1st Sess. 18-19 (1981). The Court of Appeals' egregious error and the substantial adverse effect of that error on the public health make this case appropriate for review by this Court.

The need for review is confirmed by the substantial judicial disagreement over the interpretation of Section 271(e)(1). Judge Newman dissented sharply from the denial of Lilly's suggestion for rehearing in banc (Pet. App. 10a). Prior to the Court of Appeals' decision, the district court in the instant case, as well as the only other district court to have considered the issue, concluded that Section 271(e)(1) is limited to drugs. *See* Pet. App. at 19a ("the § 271(e)(1) defense [is] inapplicable to medical devices"); *Scripps Clinic & Research Foundation v. Baxter-Travenol Laboratories, Inc.*, 7 U.S.P.Q. 2d 1562, 1565 (D. Del. 1988) ("It is also clear that Section 271(e)(1) applies only to drugs, not to medical devices." (*dictum*)).

Medical devices are subject to premarket approval and other regulation by the Food and Drug Administration ("FDA"). Prior to the Court of Appeals' decision in this case, it would have been an act of patent infringement to make, use, or sell an infringing

product in studies conducted to obtain the data necessary for FDA commercial approval for medical devices or other nondrug products. The Court of Appeals interpreted a narrow statutory exemption, which universally had been understood to apply *only* to the limited testing necessary for generic drug approvals, to encompass studies for *all* FDA-regulated products.

The Court of Appeals' decision constitutes impermissible judicial legislation. The decision substantially erodes patent protection for inventions pertaining to medical devices, food and color additives, and other FDA-regulated, nondrug products. See pages 18-20, *infra*. Under the Court of Appeals' interpretation of Section 271(e)(1), infringers are granted immunity prior to market approval to make, use, or sell these otherwise infringing products without a license from or payment of compensation to the patent holder.

II. The Court of Appeals' Decision Is Directly Contrary to the Statutory Language, Legislative History and Policy of Congress

A. Statutory Language

As recently amended to apply to certain animal drugs and biological products as well as to human drugs, 35 U.S.C. § 271(e)(1) reads as follows:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products* (emphasis added).

The ordinary meaning of the statutory language is that it applies only to "drugs" and "veterinary biological products." "Medical

devices" are not mentioned. Indeed, they are expressly excluded from the definition of "drug" under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). See 21 U.S.C. § 321(g)(1) ("The term 'drug' . . . does not include devices or their components, parts, or accessories."). Drugs and devices are regulated under entirely different statutory provisions. Compare 21 U.S.C. § 355 (drugs) with 21 U.S.C. § 360 (devices).

This should have been the end of the matter.⁶ See, e.g., *United States v. James*, 478 U.S. 597, 604-606 (1986). Straining to find an ambiguity, however, the Court of Appeals concluded that the "law which regulates" drugs or veterinary biological products meant the entire FD&C Act, including the device provisions, as well as the Act of March 4, 1913 (under which veterinary biological products are regulated). This reading is directly refuted by the plain language of the statute: a few lines earlier in Section 271(e)(1), Congress referred expressly to the "Federal Food, Drug, and Cosmetic Act" and the "Act of March 4, 1913." It is implausible, to say the least, that Congress then would have used entirely different language to describe the same statutes later in the same provision.

If Congress had intended to provide an infringement exemption for devices as well as for drugs, it would have referred to a law which regulates "drugs *and* devices." Whenever Congress limited or proposed to limit a patentee's rights under Section 271(e)(1), Congress spoke clearly. Congress used clear language to identify "drugs" under the Section 271(e)(1) exemption in the 1984 original enactment. Congress' 1988 amendment of the statute extended the exemption to certain animal drugs and veterinary biological products: Congress did so by adding the express reference to "veterinary biological products" to the end

⁶ Although the Court of Appeals did not accept the argument, Medtronic urged below that the statutory language was ambiguous because Congress referred to a patented "invention" rather than to a patented "drug." The latter term, however, could have limited the provision to product patents and excluded process patents, which Congress intended to cover. Congress therefore used the term "invention" to ensure that all types of drug patents would be included, so long as the claimed invention was used solely for purposes relating to the development of information necessary to obtain drug approval.

of Section 271(e)(1) and deleting the express exclusion for certain "animal drugs" from the "drug" category. See Pub. L. No. 100-670, § 201(i)(1), 102 Stat. 3971, 3988 (Nov. 16, 1988).⁷

When Congress enacted the 1984 law, it included protections—by specifying acts of infringement and establishing remedies—for "drug" patent holders under certain circumstances in Sections 271(e)(2) and (e)(4) (Pet. App. 62a-63a). Congress added similar protections for owners of patented animal products in the 1988 amendment to Section 271(e)(1) (*id.*). Had Congress believed that "medical devices" were within the infringement exemption of Section 271(e)(1) as originally enacted, surely Congress would have provided corresponding protections for medical device patent holders in the original enactment of Sections 271(e)(2) and (e)(4). For example, proposed Senate Bill S.622 would add "medical devices" to Sections 271(e)(2) and (e)(4) (Pet. App. 60a-61a). However, the current Sections 271(e)(2) and (e)(4) are specific to "drugs" and "veterinary biological products" and further confirm that their companion Section 271(e)(1) should be construed likewise.⁸

The Court of Appeals' decision inserts the words "medical devices" into Section 271(e)(1) without providing the additional patent protections of Sections 271(e)(2) and (e)(4). This is the worst possible result for medical device patent holders and clearly not intended by Congress.

The Court of Appeals' error is all the more apparent because its reading is not limited to devices. It applies also to every other article regulated under the FD&C Act, such as food additives,

⁷ As further confirmation, a bill pending in Congress at the time of the Court of Appeals' decision, if passed, would have amended the statute by adding the term "medical devices" to the end of Section 271(e)(1). See S. 622, 101st Cong., 1st Sess., 135 Cong. Rec. S2860-61 (daily ed. Mar. 16, 1989) (Pet. App. 60a-61a).

⁸ The district court held that "other sections of the [Drug Price Competition and Patent Term Restoration Act of 1984] distinguish between 'drugs' and 'devices', further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term 'drugs' to include 'devices'" (Pet. App. 18a).

color additives, and other substances—none of which is referred to anywhere in Section 271(e)(1). In short, the Court of Appeals expanded a statute that by its terms allowed only a narrow infringement exemption for two specifically mentioned products—drugs and veterinary biological products—to apply to medical devices and other products not mentioned anywhere in the statute itself.⁹

As Judge Newman concluded, the Court of Appeals' departure from the statutory language constitutes impermissible judicial legislation (Pet. App. 12a). See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy."); *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456, (1984), ("it is not our job to apply laws that have not yet been written"); *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written.").

B. Legislative History

The legislative history further demonstrates that Congress intended that Section 271(e)(1) would allow infringement only for drugs (and later for animal products), but not for any other FDA-regulated product. There is not a single reference in any legislative history of this provision suggesting the possibility that it would permit infringement of medical device patents.

Two committee reports were prepared on the 1984 legislation that originally enacted Section 271(e)(1): one by the House Committee on Energy and Commerce and one by the House

⁹ The Court of Appeals' reliance on *United States v. Fausto*, 484 U.S. 439 (1988) (Pet. App. 6a), does not support its departure from the statutory language. Rather, that case confirms the importance of both the language chosen by Congress and the congressional intent. The instant case does not raise any question requiring the reconciliation of interrelated laws enacted at different times. Rather, it requires only a straightforward exercise in the interpretation of Section 271(e)(1) based on its plain language and legislative history.

Committee on the Judiciary. H.R. Rep. No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984), *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647. Both reports establish that Section 271(e)(1) is directed solely to drugs. *See, e.g., id.*, Part 1, at 15 ("it is not an act of patent infringement for a *generic drug* maker to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added)); *id.*, Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval of *the drug*." (emphasis added)); *id.* ("The purpose of Section 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." (emphasis added)); *id.*, Part 2, at 27 n.18 (it would not be an infringement to use patented information "for the purpose of obtaining FDA premarketing approval of a *drug*" (emphasis added)); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to animal products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2d Sess. 13 (1986) (emphasis added).¹⁰

The Court of Appeals inexplicably dismissed these clear expressions of congressional intent as merely "general statements . . . which allegedly support" the district court's and Lilly's interpretation of the statute (Pet. App. 5a). At the same time,

¹⁰ Commentators on the 1984 legislation agreed that this provision "is limited to human drug products, and does not include medical devices. . . food additives, color additives, or other related activities." Flannery & Hutt, "Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984," 40 Food Drug Cosm. L.J. 269, 307 (1985); *accord*, Fox & Bennett, "The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984," at 178, 187 (Food and Drug Law Inst. 1987). Similarly, in their *amicus* brief supporting rehearing in the Court of Appeals, the principal Senate author of the 1984 legislation and a primary floor manager in the House stated that section 271(e)(1) was intended to permit only "use of a patented drug product, prior to the patent's expiration, for purposes relating to obtaining FDA approval." Brief of Senator Hatch and Representative Moorhead, at 1.

its opinion (*id.*) gives the erroneous impression, without citation, that there are contrary statements supporting the extension of Section 271(e)(1) to devices. There are none. *See* Pet. App. 5a-7a.

The Court of Appeals concluded *sua sponte*, however, that Section 271(e)(1) was intended to overrule the *Bolar* case, *supra*, "in all of its ramifications" (*id.* at 7a) and thereby to immunize infringement for medical devices and other products not mentioned in the statute itself, in its legislative history, or in the *Bolar* case. This interpretation defies understanding.

Congress intended that Section 271(e)(1) would "have the net effect of reversing the *holding*" in *Bolar*. H.R. Rep. No. 857, *supra*, Part 2, at 27 (emphasis added). Congress understood the court in that case to have "held that the experimental use of a *drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement." *Id.*, Part 1, at 45-46 (emphasis added); *accord, id.*, Part 2, at 27 n.18. In *Bolar* itself, the Court of Appeals stated that the issue was a "narrow" one:

does the limited use of a *patented drug* for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

733 F.2d at 861 (emphasis added). Whatever the Court of Appeals now believes its holding to have been, surely it is Congress' understanding at the time it enacted Section 271(e)(1) that is relevant.¹¹ Thus, Congress overruled *Bolar* "in that (Section 271(e)(1)) would provide that generic *drug* manufacturers can start playing around with the *drug* on which the patent is about to

¹¹ "The meaning and effect of legislation whose operation is conditioned by common-law principles are not changed by subsequent judicial decisions modifying the common-law principles." 2a *Sutherland Statutory Construction* § 50.02, at 431 (4th ed. 1984) (emphasis added). *See generally, e.g., Mackey v. Lanier Collection Agency & Service, Inc.*, ___ U.S. ___, 108 S.Ct. 2182, 2191 (1988) ("It is the intent of Congress that enacted [the section] . . . that controls.") (citations omitted).

expire." 130 Cong. Rec. H8712 (daily ed. Aug. 8, 1984) (statement of Rep. Kindness) (emphasis added).

It is difficult to imagine how Congress could have made its intentions any more clearly known. There is simply no basis for concluding that Congress intended anything more than to overrule the precise holding of *Bolar* as Congress and the *Bolar* court understood it, i.e., to prohibit the experimental use of patented drugs for FDA approval purposes. The Court of Appeals here pointed to no evidence of congressional intent, and there is none, suggesting a desire to overrule *Bolar* "in all of its ramifications." The court's *ipse dixit* thus entirely ignores the plainly expressed intention of Congress.¹²

C. Policy and Constitutional Considerations

The application of Section 271(e)(1) only to drugs, which is compelled by its language and legislative history, is further supported by important distinctions between FDA regulation of drugs and medical devices. While the Court of Appeals claimed to discern "[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only" (Pet. App. 7a), there are in fact sound policy considerations favoring this interpretation. The court apparently failed to appreciate these reasons because it lacked a sufficient understanding of the very different FD&C Act provisions and FDA regulations that govern testing and approval of drugs versus medical devices. See Judge Newman's dissenting opinion, Pet. App. 12a ("there are different considerations in connection with medical devices, as compared with human and animal drugs"). The extension of the infringement exemption to medical devices is unsupported as a matter

¹² Moreover, if Congress intended to overrule all of the "ramifications" of *Bolar*, this would eliminate the experimental-use exception to patent infringement for all inventions, not just for those pertaining to FDA-regulated products. Congress of course intended no such thing, and not even the Court of Appeals suggests that it did. Yet the court offered no justification for picking and choosing among the various "ramifications" of *Bolar* that purportedly were overruled by Section 271(e)(1). The only interpretation that can be defended on the basis of the statutory language and legislative history is that Congress intended to overrule *Bolar* as it applied to drugs.

of sound policy and serves only to retard the development of innovative health products.

New drugs are subject to premarket approval by FDA upon a showing of safety and effectiveness. See 21 U.S.C. § 355. Prior to 1984, generic copies of previously-approved drugs generally required their own approvals resting on their manufacturers' own clinical studies. See *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983). The same statute that enacted Section 271(e)(1) also established an "abbreviated" procedure for approval of generic drugs. See 21 U.S.C. § 355(j). Under this procedure, a generic applicant is not required to submit independent proof of safety and effectiveness, but need show only that its product is "bioequivalent" to the previously-approved drug—i.e., that it has the same "rate and extent of absorption" into the bloodstream. 21 U.S.C. § 355(j)(7)(B)(i).

Section 271(e)(1) permits such bioequivalence testing prior to the expiration of a drug patent. This testing is conducted in a limited number of volunteers who typically are healthy persons who do not even have the disease for which the drug is intended. These persons are not charged for the drug. Congress found that the "nature of the interference" with a drug patent holder's rights entailed by such bioequivalence testing "is *de minimis*." H.R. Rep. No. 857, Part 2, at 30.¹³

The interference with a medical device patent holder's rights, however, would be far more significant. There is no "abbreviated" procedure for approval of medical devices subject to premarket approval application requirements. See 21 U.S.C. § 360. The medical device testing that would be permitted under the Court of Appeals' decision therefore encompasses full-scale clinical trials rather than the much more limited bioequivalence testing necessary for generic drug approval.

¹³ While the statute also would permit clinical trials of patented drugs, Congress understood that, as a practical matter, manufacturers would take advantage of the much faster and less expensive "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own clinical tests in hundreds or thousands of patients. See H.R. Rep. No. 857, Part 2, at 8.

These clinical trials permit device manufacturers to introduce their products to the market by treating patients with the underlying disease and by involving leading physicians and medical institutions in the studies. Many devices, such as the implantable defibrillators at issue here, are permanently implanted and thus each patient who is treated with the investigational device is unavailable as a customer to the patent holder. Similarly, many devices, such as diagnostic machines, have only a small number of potential customers. Hospitals, for example, may need only one CAT-scan machine, and thus each hospital using an infringing device, even for "investigational" purposes, is lost to the patent holder's market.

Moreover, manufacturers charge for investigational devices, even those that infringe patents. See 21 C.F.R. § 812.7(b). Such charges are common for expensive devices such as implantable defibrillators. Medtronic, for example, sold its infringing units for \$17,000 each. (Pet.App. 12a n.4). Some medical devices may carry even higher per-item prices. Indeed, a single medical device may itself be sold for a quarter of a million dollars or more. Clinical trials by infringers could rob patent holders of millions of dollars in lost sales, while the infringers themselves recover all of their "costs of manufacture, research, development, and handling" (21 C.F.R. § 812.7(b))—all before the life of the patent has expired.

Accordingly, there are persuasive, solid reasons—rooted in the different testing procedures and approval requirements of drugs and devices—for distinguishing between them in Section 271(e)(1). Those differences raise a serious constitutional question under the takings clause of the Fifth Amendment of the U.S. Constitution if the statute is interpreted to authorize the infringing use of medical devices. Cf. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). Section 271(e)(1), as interpreted by the Court of Appeals, impermissibly takes a portion of the exclusive patent rights from medical device patent holders after a patent holder has disclosed its invention to the public. Such public disclosure is the *quid pro quo* for the exclusive patent right for the entire patent term. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, ___ U.S. ___, 109 S.Ct. 971, 977, (1989) ("The federal patent system thus embodies a carefully crafted bargain for encouraging

the creation and disclosure of new, useful, and nonobvious advances in technology in return for the exclusive right to practice the invention for a period of years.").

When it enacted Section 271(e)(1), Congress addressed this takings question as it applied to drugs, and it concluded that the statute was constitutional largely because of the "*de minimis* economic impact" on patent holders:

[T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. * * * Thus, the nature of the interference with the rights of the patent holder is not substantial.

H.R. Rep. No. 857, Part 2, at 8; see also *id.*, Part 2, at 27-30; *id.*, Part 1, at 46. The much more substantial economic impact of an infringement exemption for medical devices raises a correspondingly more substantial constitutional issue. That issue would be avoided, as it should be, by interpreting Section 271(e)(1) in accordance with its plain meaning and legislative history to apply only to drugs and veterinary biological products. See generally *Ashwander v. TVA*, 297 U.S. 288, 346-348 (1936) (Brandeis, J., concurring).

Finally, the Court of Appeals' decision will have a significant deleterious effect on medical device innovation, and therefore on the public health. The patent system is intended to provide the necessary incentive for "inventiveness and research efforts." *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980). That incentive would be seriously eroded if infringement is immunized for device testing purposes. See pages 18-20, *infra*.

At the same time that it enacted Section 271(e)(1), Congress provided for the partial extension of drug and device patents in order to "create a significant, new incentive which would result in increased expenditures for research and development" in the health-care industry. H.R. Rep. No. 857, *supra*, Part 1, at 18. While Congress was willing, as part of a compromise with generic drug interests, to make a *de minimis* exception for drug bioequivalence testing, it did not make the much larger inroad on

patent rights that a device exception would represent.¹⁴ Such an exception would eviscerate the very research incentives that Congress had intended to expand in the 1984 legislation. As Judge Newman concluded, "[t]he panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest." (Pet. App. 12a).

For all these reasons, the Court of Appeals seriously erred in departing from the plain language, legislative history and policy underpinnings of Section 271(e)(1).

III. An Exceptionally Important Federal Statutory Issue Is Before This Court

This case raises a federal statutory issue of exceptional national importance (Pet. App. 10a, 13a). The Court of Appeals determined that infringing medical devices undergoing clinical trials prior to patent expiration are entitled to a limited non-infringement defense under Section 271(e)(1).

Millions of dollars of medical devices undergoing clinical trials are sold in the United States each year. For example,

¹⁴ Contrary to arguments presented by Medtronic below, there is no indication in the legislative history that Section 271(e)(1) was intended to apply to devices as a *quid pro quo* for extension of device patent terms under 35 U.S.C. § 156(b), as enacted by the 1984 legislation. Section 271(e)(1) and Section 156(b) are not, and were never intended to be, parallel in scope. For example, Section 271(e)(1) is applicable to many patents that do not meet the numerous eligibility requirements for extension under Section 156(b). Cf. *Fisons v. Quigg*, 876 F.2d 99 (Fed. Cir. 1989) (discussing eligibility restrictions). Additionally, the Section 271(e)(1) exemption applies at any time during the life of a patent and does *not* apply *solely* during the extended period of a patent provided by Section 156(b).

The Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, 98 Stat. 1585 (1984), that enacted Section 271(e)(1) plainly was a compromise between opposing innovator pharmaceutical companies and generic drug interests. See, e.g., 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore); *id.* at H8706-07 (daily ed. Aug. 8, 1984) (statements of Reps. Kastenmeier and Waxman). There is no indication that device manufacturers had any part in the legislative compromise or were granted any special exemption by Congress in the legislation.

Medtronic sells its infringing devices for \$17,000 per unit *during clinical trials* (Pet.App. 12a n.4). Medtronic projected its cumulative revenue from the sale of infringing devices manufactured in the United States through its fiscal year of 1990 in the amount of \$11 million—all, according to Medtronic, during clinical trials (*id.*). Other competitors also would be encouraged to enter into or continue similar clinical trials based upon the Court of Appeals' decision. Thus, the total pre-expiration sales of infringing devices (and direct loss of sales to Lilly's subsidiary, CPI) using the basic patent in this suit could be several times the amount projected by Medtronic. Under the guise of "research" or "experimentation," competitors could erode twenty-five percent or more of Lilly's market—prior to the expiration of the patents in suit—in the name of "clinical testing."

This example, of course, relates to just one patent in a particular medical device field. With the development of medical devices in the broad areas of heart-assist devices, lung and kidney devices, and the literally unlimited number of other medical devices, the decision of the Court of Appeals takes on great public significance in the medical device field alone. For expensive, long-lasting devices for which the number of potential customers is relatively small, the sale of such devices during the investigational period (for example, the sale of CAT-scanners, x-ray and ultrasound machines, and other diagnostic machines to hospitals) may erode substantially the market for a patented device even prior to FDA approval.

The Court of Appeals' decision will discourage precisely what the patent laws are intended to encourage—innovation, technological development, and investment in high-risk ventures, such as the automatic implantable cardioverter defibrillator. The Court of Appeals' decision will encourage copying instead. The decision will also increase federal patent litigation by encouraging infringement, and by spawning numerous and complex disputes over whether particular activities come within the exemption of Section 271(e)(1).

The investment community will view medical device patents as high-risk properties of doubtful value. Money needed to develop promising inventions will be diverted away from pioneering inventors and directed to copiers and infringers after the inventor

and his investors have taken the risk to establish the success of the invention. On the day of the Court of Appeals' decision, Medtronic's stock "soared 4-1/2 to 87-1/2 before trading was halted later in the session. . . ." *Wall Street Journal*, March 30, 1989, p. C2.

In a technology-driven industry, such as the field of automatic implantable defibrillators and other high-technology medical devices, a company's technical reputation benefits all of its product lines. Medtronic recognized the importance of technological reputation by proclaiming itself the "technological leaders in the tachy arena" after only the first clinical-trial implant of its infringing defibrillator (Trial Ex. 143). The ripple effect of this reputation, which can be secured during clinical trials by courting key opinion leaders, is to: (1) open customer doors previously closed for other products; (2) attract new research talent and leadership; and (3) obtain access to the *limited* number of clinical sites, key physician investigators, and suitable patients for clinical trials (Hauser Trial Test, Day 16, pp. 20-21; Luceri Trial Test, Day 4, pp. 139-40). The Court of Appeals' decision deprives medical device patent holders of these benefits afforded a patent owner for its *exclusive* patent rights.¹⁵

¹⁵ By losing its exclusive patent position and the benefits arising from the exclusive patent rights, Lilly is being irreparably harmed. The district court concluded that, without an injunction, Medtronic would use "its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation" (Pet. App. 37a). The district court found that Lilly "will be irreparably harmed if Medtronic is not enjoined from further infringement of Lilly's patents" (*id.*).

CONCLUSION

The Court of Appeals' decision is erroneous. Congress has not enacted the law that the Court of Appeals has legislated. Injustice has resulted to patent holders for FDA-regulated medical devices and other nondrug products, to the long-term detriment of the public health.

For the foregoing reasons, this petition for certiorari should be granted. Because the Court of Appeals' decision is so clearly erroneous, summary reversal is appropriate.

Respectfully submitted,

Dated: August 10, 1989

/s/ TIMOTHY J. MALLOY

TIMOTHY J. MALLOY
Counsel of Record

LAWRENCE M. JARVIS

GREGORY J. VOGLER

MCANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

APPENDIX

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

DECIDED: March 29, 1989

Before NIES, *Circuit Judge*, COWEN, *Senior Circuit Judge*, and
ARCHER, *Circuit Judge*.

NIES, *Circuit Judge*.

Medtronic, Inc., brings an interlocutory appeal from a permanent injunction¹ entered by the United States District Court for the Eastern District of Pennsylvania, *Eli Lilly & Co. v. Medtronic, Inc.*, No. 83-5393 (E.D. Pa. Apr. 21, 1988) (Ditter, J.), enjoining it from, *inter alia*, the manufacture, use, or sale of certain medical devices, and from the use of data generated from such medical devices. Medtronic asserts that 35 U.S.C. § 271(e)(1) (Supp. III 1985) permits the use it is making of its medical devices, namely, for testing and obtaining certain approval by the Food and Drug Administration (FDA). Prior to trial, the district court had ruled that that statute applies to drug products only; Medtronic could not, therefore, assert it as a defense against Lilly's charges of infringement. *See Eli Lilly & Co. v. Medtronic, Inc.*, 5 USPQ2d 1760 (E.D. Pa. 1987). We disagree. Accordingly, we reverse the court's ruling that 35 U.S.C. § 271(e)(1) is restricted to drugs, and we remand for determination of whether, in fact, Medtronic's use of its medical devices falls under section 271(e)(1). Because it is unclear that all of Medtronic's activities fall within

¹ This court has jurisdiction over this appeal pursuant to 28 U.S.C. §§ 1292 (a) (1) and (c) (1) (1982).

the section 271(e)(1) exception, we leave it for the court on remand to decide to what extent the injunction should be vacated, modified, or stayed during further proceedings.

I

As an initial matter, we note that the propriety of the grant or denial of an injunction under 35 U.S.C. § 283 (1982) is reviewable under an abuse of discretion standard. *Windsurfing Int'l. v. AMF Inc.*, 782 F.2d 995, 1002, 228 USPQ 562, 567 (Fed. Cir.), *cert. denied*, 477 U.S. 905 (1986). However, abuse of discretion may be established by showing an injunction is based upon a misinterpretation of applicable law. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988) (quoting *PPG Indus. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1572, 6 USPQ2d 1010, 1016 (Fed. Cir. 1988) (Bissell, J., additional views)). Here, we conclude that the district court interpreted 35 U.S.C. § 271(e)(1) too narrowly.

II

BACKGROUND

Lilly sued Medtronic for infringement of claims 1-6 of its U.S. Patent Re. No. 27,757 and claim 1 of U.S. Patent No. 3,942,536 under 35 U.S.C. § 271(a) (1982). Lilly alleged that Medtronic's development and marketing of its automatic implantable cardioverter defibrillators and catheter electrodes infringed Lilly's patents covering such medical devices. Medtronic asserted the statutory noninfringement defense provided by 35 U.S.C. § 271(e)(1), and moved for partial summary judgment on that basis. *See Eli Lilly & Co.*, 5 USPQ2d 1760. The court denied Medtronic's motion, ruled that section 271(e)(1) does not apply to medical devices, and prohibited Medtronic from presenting evidence at trial regarding the section 271(e)(1) defense. *Id.* at 1762. Following a trial on the merits, which resulted in Medtronic being held to infringe Lilly's patents, the district court reaffirmed its interpretation of section 271(e)(1) and issued the subject injunction. *See Eli Lilly & Co. v. Medtronic, Inc.*, 696 F. Supp. 1033, 7 USPQ2d 1439 (E.D. Pa. 1988).

III

This case raises a question of first impression, namely, whether the noninfringement defense of 35 U.S.C. § 271(e)(1), added by amendment in 1984, applies to medical devices.

Shortly before section 271(e)(1) was enacted, this court addressed whether it was an infringing use under 35 U.S.C. § 271(a)² for a nonlicensee to use a patented drug product, prior to the patent's expiration, for purposes strictly related to obtaining FDA approval for a generic substitute intended to be sold commercially, only after the patent expires. The case addressing that issue was *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). This court in *Roche* concluded that such use did not fall within any established experimental use exception and declined to extend or create an experimental use exception for FDA testing. The court noted that Congress was the appropriate forum to resolve the matter and that legislation was pending on related subjects which made it aware of the problem. *Id.* at 865, 221 USPQ at 942. Under the *Roche* ruling, infringement would be found for the investigational testing of an infringing medical device even though, under 21 U.S.C. § 360e (1982 & Supp. III 1985) of the Federal Food, Drug, and Cosmetic Act, such testing is required to obtain FDA approval to market such devices.

The *Roche* decision resulted in an immediate effort by the generic drug manufacturers to escape the effect of the decision. An amendment of the patent statute was put forth in connection with the pending legislation noted in the *Roche* decision.³ Before Congress, those interests urged that the time required to obtain FDA approval for their generic products, if they had to wait to begin testing until after a patent expired, gave an effective

² Section 271(a) provides: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

³ The pending legislation provided for abbreviated testing procedures for generic drugs. H.R. 3605, 98th Cong., 1st Sess. (1983) ("Drug Price Competition Act of 1983").

extension of the patent term, which was contrary to the interests of the public in obtaining lower cost drugs as soon as possible. It was an objective of the generic drug manufacturers to be able to place their generic substitutes for a patented drug on the market the day after the patent expired. That objective could be achieved only if they were able to acquire data and apply to FDA prior to that time, activities which were legally impermissible under *Roche*. At the same time, Congress had before it bills supported by the proprietary drug interests which had as their objective the extension of the patent term. The justification for such extension also lay in the FDA testing requirements which consumed, in many instances, a number of years of the patent term and effectively reduced the patentee's time for exclusive commercial exploitation of the invention.

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the Act), signed into law in 1984, simultaneously effected some of the aforementioned objectives. The Act overruled *Roche* by adding section 271(e)(1) to title 35 which reads⁴ in pertinent part:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Section 271(e)(3) (Supp. III 1985) further provides:

In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

⁴ On November 16, 1988, President Reagan signed Public Law No. 100-670, entitled the "Generic Animal Drug and Patent Term Restoration Act," into law. Although that law amends 35 U.S.C. § 271(e)(1), the amendment does not affect our analysis here.

Conduct within the ambit of section 271(e)(1) is not an act of infringement, and, hence, cannot be enjoined pursuant to section 271(e)(3). This appeal raises the question of whether section 271(e)(1) is a limited exception which applies only to drugs, as the district court ruled, or applies generally to patented inventions, including medical devices.

In the patent term restoration portion of the legislation, which became codified in 35 U.S.C. § 156 (Supp. III 1985), the benefits of patent extension are not restricted to drugs, but extend to medical devices. See 35 U.S.C. § 156(f)(1)(B).⁵

IV

Each of the parties has urged that the above-quoted statutory language of 35 U.S.C. § 271(e)(1) is "clear." However, each has put forth equally plausible interpretations of section 271(e)(1), which to us means the language is fraught with ambiguity. The district court and Lilly limit the exception for "patented inventions" to patented *drugs* by reading the last clause of 271(e)(1) as a restriction on that otherwise broad statutory language. Medtronic urges that the exception extends to all types of "patented inventions" provided the use being made is for testing to obtain approval from FDA for sale of a product after the relevant patent has expired. Per Medtronic, the last clause describes the type of law, not the type of patented invention. Furthermore, as is often the case, each side has been able to highlight general statements in the legislative history which allegedly support their own reading of section 271(e)(1). However, amidst ambiguous language in the statute, and ambiguous statements in the legislative history, what is clear to this court, as well as to the parties and the district court, is that section 271(e)(1) was added to overrule this court's decision in *Roche*.

⁵ 35 U.S.C. § 156 (f)(1)(B) defines the word "product" for which the term of a patent may be extended to include:

Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.

While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. § 271(a) without regard to what particular goods might be involved. Specifically, the court decided that the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for a substitute, was an infringement under 35 U.S.C. § 271(a). Apart from *Roche*, there is no other precedent directly on the point.

Congress explicitly stated: "The provisions of section 202 of the bill [i.e., the amendment of Title 35 adding section 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 27, reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2711. The clear intent of Congress was to create an FDA experimental use exception for use which *Roche* had held would constitute infringement under section 271(a)(1). *Id.*, pt. 1 at 45-46, reprinted at 2678-79. The effect of the section 271(e)(1) amendment as a restriction on section 271(a) is comparable to the interrelationship of statutes addressed by Justice Scalia in *United States v. Fausto*, 108 S. Ct. 668 (1988). There he points out that:

Repeal by implication of an express statutory text is one thing; it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change. . . . But repeal by implication of a legal disposition implied by a statutory text is something else. The courts frequently find Congress to have done this—whenever, in fact, they interpret a statutory text in the light of surrounding texts that happen to have been subsequently enacted. This classic judicial task of reconciling many laws enacted over time, and getting them to "make sense" in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. And that is what we have here.

108 S. Ct. at 676. This is what we have here as well. No statutory language is section 271(a) is repealed by implication. Rather, the *Roche* interpretation of the language of section 271(a) is necessarily repealed (that is, by implication) by the addition of

section 271(e)(1). In overturning *Roche*, Congress eliminated *certain activity* as being infringing. No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation. Further, it simply makes no sense to apply *Roche* as precedent to nondrug products when the case has no precedential value as to the specific products of the *Roche* suit, namely, drugs. We can only conclude that Congress intended the enactment of section 271(e)(1) to set aside the *Roche* interpretation of section 271(a) in all of its ramifications. Accordingly, we hold that section 271(e)(1) allows a party to make, use, or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

Relief

The court indicated, when deciding Medtronic's summary judgment motion regarding the availability of section 271(e)(1) as a defense, that a genuine issue of material fact exists as to whether Medtronic's use of its devices was "*solely* for purposes reasonably related to submission of information" to the FDA. *Eli Lilly & Co.*, 5 USPQ2d at 1761 n.6. Accordingly, we remand this case to the district court for determination of that factual issue. Because we are not certain whether Medtronic's section 271(e)(1) defense, if valid, goes to the entirety of its otherwise infringing activities, we leave it to the district court to decide whether the injunction should be vacated, modified, or stayed while the trial of the above issue is proceeding.

Costs

Each party shall bear its own costs.

REVERSED AND REMANDED

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
*Defendant-Appellant.*Before NIES and ARCHER, *Circuit Judges*, and COWEN, *Senior Circuit Judge*.

ORDER

A petition for rehearing having been filed in this case, a response thereto having been invited by the court and filed, two amicus curiae briefs in support of the petition for rehearing and two amicus curiae briefs in opposition to the petition for rehearing having been filed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, denied.

The suggestion for rehearing in banc is under consideration. The mandate will issue on June 7, 1989.

FOR THE COURT

/s/ FRANCIS X. GINDHART

 FRANCIS X. GINDHART
CLERK

May 31, 1989

 cc: PHILIP S. JOHNSON
TIMOTHY J. MALLOY
PAUL DAVID SCHOENLE
CARLOS J. MOORHEAD
ORRIN G. HATCH
MICHAEL I. RACKMAN
GEORGE GERSTMAN

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
- 88-1409ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

CORRECTED ORDER

A suggestion for rehearing in banc having been filed in this case, a response thereto having been invited by the court and filed, and two amicus curiae briefs in support of the suggestion for rehearing in banc and two amicus curiae briefs in opposition to the suggestion for rehearing in banc having been filed,

UPON CONSIDERATION THEREOF, it is

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, declined.

FOR THE COURT

/s/ FRANCIS X. GINDHART

 FRANCIS X. GINDHART
CLERK

July 18, 1989

 cc: PHILIP S. JOHNSON
TIMOTHY J. MALLOY
PAUL DAVID SCHOENLE
CARLOS J. MOORHEAD
ORRIN G. HATCH
GEORGE GERSTMAN
RONALD L. HEMINGWAY
MICHAEL I. RACKMAN

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

NEWMAN, *Circuit Judge*, dissenting from the denial of rehearing in banc.

In view of the exceptional importance of the matter, Fed. R. App. P. 35, and the weight of the panel's error, I respectfully dissent from the court's denial of rehearing in banc.

The panel, reversing the judgment of the district court, held that the statutory words "drugs or veterinary biological products" include medical devices.

The statute with which the panel was dealing, as enacted in 1984, was explicitly limited to "the manufacture, use, or sale of drugs".¹ The legislative history stated:

The purpose of Section 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. [emphasis added]

¹ P.L. 98-417, codified at 35 U.S.C. § 271(e) (1):

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs*. (emphasis added) 35 U.S.C. § 271(e) (1) (Supp. II 1984).

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 45, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2678.

By congressional action in 1988, after hearings, the statute was extended to animal drugs and veterinary biological products.² At the time of the panel's decision in March 1989 there was pending legislation to extend the statute to medical devices. Congress had scheduled hearings. On introducing S.622 Senator DeConcini stated:

The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medical devices and this must be clarified.

135 Cong. Rec. S2861 (daily ed. Mar. 16, 1989).

The panel held that the statute already covered medical devices.

The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs. *Eli Lilly and Co.*

² P.L. 100-670, the present text of 271 (e) (1):

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs or veterinary biological products*. (emphasis added) 35 U.S.C.A. § 271(e) (1) (West Supp. 1989).

v. Medtronic Inc., 5 USPQ2d 1760, 1761-62 (E.D. Pa. 1987).³

In *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456, 220 USPQ 665, 684 (1984), the Supreme Court again cautioned the judiciary that

it is not our job to apply laws that have not yet been written.

The panel stated that it was implementing congressional "intent". It is indeed possible that Congress would have amended the statute to include medical devices. However, the legislation had not yet been enacted. It is for Congress, not the courts, to change the law for policy reasons. *Sony, supra*; *BankAmerica Corp. v. United States*, 462 U.S. 122, 140 (1983) (the Supreme Court is not to rewrite a statute based on its notions of appropriate policy); *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply statutes on the basis of what Congress has written, not what Congress might have written").

The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and amici on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs.⁴ Congress would be expected to consider the public

³ Another district court has identically interpreted the statute. *Scripps Clinic and Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 USPQ2d 1562, 1565 (D. Del. 1988) ("It is also clear that section 271(e) (1) applies only to drugs, not to medical devices.")

⁴ It is undisputed that the Medtronic devices (cardioverter defibrillator units) infringe the Lilly patent, that the devices are sold at \$17,000 each, that eleven million dollars of infringing sales are projected through 1990, and that this activity began early in the patent life, well before patent expiration. These circumstances, while specific to the case at bar, lend weight to Lilly's position that pre-registration activity for medical devices is significantly different from that for human and animal devices.

I remark on the anomaly whereby sales of unregistered medical devices may now be deemed non-infringing for as long as they are unregistered. This curious outcome would surely have been explored at congressional hearings.

and private economic and policy aspects of these complex industries. I can not imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the court to amend statutes under the guise of 'statutory interpretation'"); *Hobbs v. McLean*, 117 U.S. 567, 579 (1886) ("When a provision is left out of a statute either by design or mistake of the legislature, the courts have no power to supply it. To do so would be to legislate, and not to construe.") Yet the panel concluded not only that Congress intended to view these industries in exactly the same way, but that this intent was already enacted into law.

This is not a matter of imprecise or ambiguous words. The clarity of the words is unchallenged. Scant respect has been accorded our admonition in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 865, 221 USPQ 937, 942 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984), wherein this court wrote:

No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation.

• • •

The Federal Circuit has a role in our judicial system that is unique among the circuits, in that our decisions are of national effect. There rests upon us a special responsibility, for there is no other forum in which litigants may seek a different result. We must be vigilant to our own errors, and receptive to self-correction. Both the principle, and the specific question here raised, are of exceptional importance, and require rehearing by the full court.

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA in CASE NO(S). 83-5393.

This CAUSE having been heard and considered, it is ORDERED and ADJUDGED: REVERSED AND REMANDED

ENTERED BY ORDER
OF THE COURT

/s/ FRANCIS X. GINDHART

FRANCIS X. GINDHART
CLERK

Mar 29, 1989

ISSUED AS A MANDATE: June 8, 1989

APPENDIX E

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

MEDTRONIC, INC.,
Defendant.

CIVIL ACTION
No. 83-5393

MEMORANDUM AND ORDER

DITTER, J.

December 4, 1987

Plaintiff Eli Lilly & Co. (Lilly)¹ brought this action against defendant Medtronic, Inc. (Medtronic), charging Medtronic with infringement of two of its patents, U.S. Patent Reissue No. 27,257 and U.S. Patent No. 3,942,536, in violation of the U.S. Patent Act, 35 U.S.C. 271(a) (1982).² Lilly contends that Medtronic's development and marketing of its automatic implantable cardioverter defibrillators and catheter electrodes has infringed Lilly's patents covering such devices.³ Medtronic argues, however, that §271(e)(1) of the Patent Act provides it a statutory noninfringement defense to any claim of infringement and has moved

¹ The original plaintiff in this action was Intec Systems, Inc. After Intec Systems was acquired by Eli Lilly & Co., Lilly was substituted as plaintiff by stipulation of the parties.

² 35 U.S.C. §271(a) provides: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent. 35 U.S.C. §271(a) (1982).

³ These devices identify and correct ventricular tachyarrhythmias. They consist of a defibrillating or cardioverting system which uses a single intravascular catheter electrode to discharge electrical energy into an ailing heart, thereby eliminating the fibrillation of the heart and decreasing cardiac mortality in patients. Plaintiff's Complaint para. 13.

for partial summary judgment on this issue.⁴

Section 271(e)(1) of the Patent Act provides:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

35 U.S.C. §271(e)(1) (Supp. III 1985). In any action for patent infringement, §271(e)(3) further provides that "no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1)." *Id.* §271(e)(3). Activities which fall within the protection of §271(e)(1) are, thus, exempt from any charge of infringement.

Congress enacted §271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (the Act), Pub. L. No. 98-417, 98 Stat. 1585. As the legislative history indicates, the enactment of the section was in response to the concern within the pharmaceutical industry and the public that the arrival of generic drugs on the market was being delayed since the bioequivalency testing required by the Food and Drug Administration (FDA) of such drugs could not begin until the expiration of the patents covering the patented equivalents of the generic drugs. See e.g., H.R. Rep. No. 98-857, 98th Cong., 2d Sess., reprinted in 1984 U.S. Code Cong. & Ad. News 2647, 2678-79, 2692-93. Much of this concern stemmed from the United States Court of Appeals for the Federal Circuit's decision in *Roche*

⁴ The parties agree that the applicability of 271(e)(1) to medical devices is an issue of first impression for this court and for any court in the country. While the district courts in *Eli Lilly & Co. v. Premo Pharmaceutical Laboratories*, No. 78-2589 (D.N.J. March 27, 1987) and *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987) addressed the applicability of §271(e)(1), they did so in the context of human drug products rather than medical devices. Those decisions, thus, are inapplicable to this case.

Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (Fed. Cir.) cert. denied, 469 U.S. 856 (1984). In *Bolar*, the defendant obtained a patented drug in order to conduct bioequivalency tests of its generic version of the patented drug. The Federal Circuit held this use of the patented drug infringing under the Patent Act, notwithstanding that it was limited to testing and investigation strictly related to FDA approval. *Bolar*, 733 F.2d at 862-63. To prevent this result, §271(e)(1) overruled *Bolar* by providing that use of a patented invention solely for purposes relating to the reporting requirements of federal drug laws is not infringement of a patent, thus allowing the use of a patented drug for bioequivalency testing of a generic drug. The 1984 Act further authorizes an abbreviated new drug application under the Federal Food, Drug, and Cosmetic Act (FFDC Act), 21 U.S.C. §301-392 (1982 & Supp. III 1985), for generic drugs, thereby hastening their introduction into the marketplace.⁵

Medtronic contends that §271(e)(1)'s noninfringement defense prevents Lilly from recovering for infringement of its patents because Medtronic's uses of its allegedly infringing devices occurred solely for purposes reasonably related to its submission of information regarding the devices to the FDA under the FFDC Act. It is Lilly's contention, though, that §271(e)(1), referring as it does to the submission of information under a federal law regulating "drugs" is wholly inapplicable as a defense for the infringing use of devices such as Medtronic's. Since I find that the statutory language of §271(e)(1) and the

⁵ Title II of the Act, which contains §271(e)(1), also restores part of the patent protection lost by new drugs, human biological products, medical devices, and food and color additives as a result of FDA pre-market testing and approval requirements. Under current patent law, a patent continues to run while the maker of the product is testing and awaiting approval by the FDA to market it. Because of the FDA testing and approval requirements, the effective life of the patent and the protection it gives the patentee from infringement of his product is often much less than the 17 years provided under the patent law. See Flannery and Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 301 (1985). To recoup some of the protection-time lost by patentees to the FDA requirements, the Act provides for extension of a patent term of up to 5 years. See 35 U.S.C. §156 (Supp. III 1985).

legislative history of the section support Lilly's contention that §271(e)(1) is inapplicable to medical devices, I will deny Medtronic's motion for partial summary judgment.⁶

The statutory language of §271(e)(1) clearly speaks in terms of the submission of information under a federal law regulating "drugs". Medtronic's invitation to construe the term "drugs" to include federal laws regulating both drugs or devices must be rejected. The FFDC Act itself defines "drugs" as excluding devices or their component parts or accessories. 21 U.S.C. §321(g)(1) (1982). While the FFDC Act undoubtedly is a federal law which by its terms regulates both drugs and devices, there is no indication in the statutory language of §271(e)(1) that the phrase "Federal law which regulates . . . drugs" was meant to include anything but drugs as they are defined by the FFDC Act, and not both "drugs" and "devices". Moreover, within the FFDC Act itself, separate and distinct procedures apply with regard to the manufacture, use, and sale of drugs and the manufacture, use, and sale of devices. See, e.g., 21 U.S.C. §355(b) and (j) (1982 and Supp. III 1985) (application for approval of new drugs); 21 U.S.C. §360j(g) (1982) (exemption for devices for investigational use). Finally, other sections of the 1984 Act distinguish between "drugs" and "devices", further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term "drugs" to include "devices".⁷

More compelling, perhaps, than the statutory language of §271(e)(1), however, is the legislative history of the section itself.

⁶ Even were I to hold §271(e)(1) applicable to medical devices, a genuine issue of material fact exists as to whether Medtronic's use of its devices was solely for purposes reasonably related to submission of information under the federal drug laws, thereby precluding summary judgment on this issue. See *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987).

⁷ For example, the patent extension section of the 1984 Act extends the patent life for inventions covering certain "products." "Products" are then defined to include a human drug product or any medical device, food additive or color additive. 35 U.S.C. §156 (f)(1) (Supp. III 1985).

Repeatedly the House report⁸ indicates that the specific purpose of §271(e)(1) was to overrule the *Bolar* decision and allow the bioequivalency testing of generic drugs without fear by manufacturers of patent infringement. Emphasizing the limited nature of the exemption, the House Report states that the purpose of §271(e)(1) "is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 98-857, 98th Cong., 2d Sess., reprinted in 1984 U.S. Code Cong. & Ad. News 2647, 2678. Nowhere in the legislative history is there any indication that Congress had a broader intention to include medical devices within the coverage of §271(e)(1). Rather, the legislative history evinces the narrow purpose of Congress to advance the quickened entry of generic drugs onto the market through unhampered bioequivalency testing. Similar testing, it is worthwhile to note, is not required of medical devices.⁹

Medtronic argues, finally, that §271(e)(1) is the quid pro quo for the patent extension granted by the 1984 Act. That is, Medtronic contends that in exchange for the grant of patent extension, Congress made available to both manufacturers of drugs and of medical devices the defense of §271(e)(1). There is no support for this contention in either the statutory language of the 1984 Act or its legislative history. Further, were I to accept Medtronic's broad construction of §271(e)(1), I would be removing the very protection which Congress sought to give patentees through the patent extension provision and through the Patent Act generally. Section 271(e)(1), as drafted by Congress, is but a narrowly-drawn exception to this protection.

Having determined the §271(e)(1) defense inapplicable to medical devices, I will, therefore, preclude defendants' presenting evidence at trial in this regard.

An appropriate order follows.

⁸ No Senate or Conference Committee Report on the 1984 Act was issued.

⁹ While medical devices are indeed subjected to periods of FDA pre-approval testing, such testing does not involve the comparison of an unpatented device with its patented prototype, as is the case with bioequivalency testing of generic drugs.

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN DISTRICT
OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

ORDER

AND NOW, this 4th day of December, 1987, for the reasons stated in the accompanying memorandum, it is hereby ordered:

1. Defendant Medtronic, Inc.'s motion for partial summary judgment is denied.
2. The statutory infringement defense of 35 U.S.C. §271(e)(1) does not apply to medical devices.
3. Defendant is precluded from presenting at trial evidence regarding the §271(e)(1) defense.

BY THE COURT:

APPENDIX F

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN
DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,

v.

Civil Action No. 83-5393
Philadelphia, Pennsylvania
Friday, April 15, 1988

MEDTRONIC, INC.,

TRANSCRIPT OF THE COURT'S FINDINGS OF FACT
and CONCLUSIONS OF LAW
BEFORE THE HONORABLE J. WILLIAM DITTER, JR.
UNITED STATES DISTRICT COURT JUDGE

APPEARANCES:
COUNSEL FOR
PLAINTIFF:

TIMOTHY J. MALLOY, ESQUIRE
GREGORY J. VOGLER, ESQUIRE
CHARLES SHIFLEY, ESQUIRE
Of Allegretti, Newitt, Witcoff &
McAndrews, Ltd.
125 South Wacker Drive
Chicago, Illinois 60606

COUNSEL FOR
DEFENDANT:

PHILIP S. JOHNSON, ESQUIRE
ALBERT W. PRESTON, JR., ESQUIRE
GARY LEVIN, ESQUIRE
Of Woodcock, Washburn, Kurtz,
Mackiewicz & Norris
One Liberty Place, 46th Floor
Philadelphia, Pennsylvania 19103

(Whereupon, the Court began proceedings at 10:40 a.m.)

THE COURT: Good morning, gentlemen.

MR. MALLOY: Good morning.

MR. JOHNSON: Good morning.

THE COURT: The jury returned its verdict in this case on March the 23rd, and on March the 25th, I heard argument concerning whether there was inequitable conduct on the part of the plaintiff and whether plaintiff is entitled to an injunction.

I have concluded that there was no inequitable conduct on the part of the plaintiff and that would be the subject of a separate memorandum which I believe will be issued next week.

I also conclude that the plaintiff is entitled to an injunction and in that regard, I will make findings of fact and conclusions of law on the record at this time. Although I have had the benefit of the transcript in the preparation of these findings of fact and conclusions of law, if it is necessary to do so, I will supplement both the findings of fact and conclusions of law at a later time.

By way of introduction. The plaintiff, Eli Lilly and Company, brought this suit against defendant, Medtronic Incorporated, alleging infringement by Medtronic of two United States patents, No. Re 27,757 re-examined and issued as Bl Re 27,757, which I will refer to as simply the '757 patent, and No. 3,942,536, re-examined and issued as Bl 3,942,536 which I will refer to as the '536 patent.

After a month long trial, I granted Lilly's motion for a directed verdict with regard to the validity of the '536 patent and its infringement by Medtronic.

The jury subsequently returned a verdict in favor of Lilly having found Medtronic's devices to infringe the '757 patent. Lilly has requested an injunctive relief against Medtronic.

In connection with Lilly's motion, I make the following findings of fact:

Plaintiff, Eli Lilly and Company, is a company incorporated in Indiana with its place of business in Indianapolis.

The defendant, Medtronic, Incorporated, is a corporation incorporated in Minnesota with its principal place of business in Minneapolis.

The '757 patent is for a defibrillator which automatically monitors the heart and provides an electrical shock to the heart if ventricular tachycardia or ventricular fibrillation occur. The purpose of the shock is to cause the heart to return to normal, rhythmic beating.

The '536 patent is for the associated intravascular catheter or lead used with the defibrillator to carry the heart-shocking electrical energy from the defibrillator to the heart. The '536 patent provides for at least two heart-shocking electrodes disposed on the same lead, one in a chamber of the heart to be defibrillated and the other outside that chamber.

Dr. Michel Mirowski is the owner of both patents-in-suit.

Lilly is the exclusive licensee of Dr. Mirowski. Lilly has sublicensed its subsidiary Cardiac Pacemakers, Inc., which I will refer to as CPI, to manufacture and sell products embodying the inventions of the patents in suit.

The Food and Drug Administration has approved the use of the devices manufactured by Lilly and CPI under the patents in suit for the treatment of ventricular tachycardia and ventricular fibrillation, two life-threatening arrhythmias, in patients who are at high risk of sudden cardiac arrest.

Ventricular tachycardia is the abnormally rapid beating of the ventricles of the heart.

Ventricular fibrillation is the rapid, disorganized contraction or fluttering of the ventricles of the heart. Ventricular tachycardia frequently leads to ventricular fibrillation if it is not treated.

Since the heart does not pump appreciable amounts of blood during ventricular fibrillation, ventricular fibrillation is always critical and usually fatal unless it is treated.

In the United States alone, up to 450,000 deaths a year are caused by sudden cardiac arrest attributable to ventricular tachycardia or ventricular fibrillation. Those patients who

survive an episode of sudden cardiac arrest have a survival rate ranging from 30 to 60 percent during the first year after that episode.

Conventional drug therapy is often not capable of treating many surviving patients and preventing an episode of sudden cardiac arrest.

Patients who have survived an episode of ventricular tachycardia or ventricular fibrillation and who receive a CPI implantable defibrillator have a survival rate of 95 to 98 percent for the first year after their initial episode.

The device produced by Lilly and CPI under the '757 and '536 patents is an automatic implantable defibrillator and its associated lead.

Medtronic, a leading producer of cardiac pacemakers, and of other medical devices, previously held a license from Dr. Mirowski for the patents-in-suit.

Medtronic returned Dr. Mirowski's patent rights in September, 1972, having decided not to develop Dr. Mirowski's invention on a commercial basis.

In 1979, Medtronic attempted to acquire Dr. Mirowski's patent rights or to reacquire Dr. Mirowski's patent rights, but was unsuccessful.

Medtronic began the first manufacture, use and sale of its model 7210 cardioverter and lead model 6882 in mid-1983.

The model 7210 and its lead, an implantable unit, was intended to treat tachycardia.

Sixteen units of Medtronic's 7210 with the model 6882 lead were implanted in human beings in the United States.

Medtronic abandoned production of the model 7210 and has no plans to make, use or sell its model 7210 in the future.

Around June, 1987, Medtronic began the manufacture, use and sale of its Model 7215 cardioverter, a defibrillation device with its associated leads, model 6891, 6892, 6893 and 6917. Model 7215 is an automatic implantable defibrillator which also includes

a bradycardia pacemaker.

The Model 7215 is designed to treat bradycardia, ventricular tachycardia and ventricular fibrillation.

Medtronic has implanted four Model 7215 with their associated leads in human beings in Canada.

During the course of this litigation, on December 6, 1985, Medtronic initiated re-examination of the '757 patent and the '536 patent in the United States Patent and Trademark Office, which I will refer to as the PTO.

In my order of January 10, 1986, I stayed this present litigation, pending the outcome of the re-examination proceedings and ordered that the parties were to be bound by the ruling of the PTO on the specific issues decided by the PTO.

I further ordered that the parties would not be bound with respect to issues which the PTO is not empowered to decide on re-examination or which it in fact did not decide during the course of its re-examination.

The validity of the claim of the '757 patent in light of the prior art listed in the re-examination certificate was determined during the course of the re-examination proceedings, and Claims 1 to 3, 5 and 6 were allowed without change. Claim 4 was amended to include the phrase, "through electrodes, with electrical energy applied directly to the heart."

The validity of the claims of the '536 patent in light of the prior art listed in the re-examination certificate was determined during the re-examination proceedings, and Claim 1 was allowed without change.

During the re-examination, the PTO determined that the only disclosure of "implantability" in the '757 patent specification is "that at least one electrode is adapted to be positioned within the heart."

The PTO also decided that the claims of the '757 patent are not limited to the concept of a "totally implantable device."

Claim 1 of the '757 patent provides for a device for automatically cardioverting a malfunctioning heart. The device is

to be comprised of a means for continually sensing the function of a heart, with means for discriminating between normal and abnormal heart function, a means for storing electrical energy for cardioverting, an electrode means for connecting the storage means directly to the heart with at least one of the electrodes to be positioned within the heart, and a means for automatically switching the storage means into a discharge state in response to an abnormal condition indication from the discriminatory means, resulting in application of the stored electricity directly to the heart through the electrodes.

Claim 2 of the '757 patent provides a means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of the electricity to the heart.

Claim 3 of the '757 patent provides for a means for inhibiting the discharge of the storage means under the conditions of normal heart activity.

Claim 4 of the '757 patent provides for the method of automatically sensing and cardioverting a malfunctioning heart. The method comprises a step of continually sensing the function of the heart, discriminating between normal and abnormal heart function, automatically starting a cycle for shocking the heart in response to the sensing of abnormal function, shocking the heart through electrodes, with electrical energy applied directly to the heart to cause cardioversion and inhibiting the shocking cycle under conditions of normal heart function.

Claim 5 provides for a device for automatically cardioverting a malfunctioning heart. The device is to be comprised of a means for continually sensing the function of the heart, with means for discriminating between normal and abnormal heart functions, a means for storing electrical energy for cardioverting, an electrode means for connecting the storage means into a discharge state whereby the stored energy is applied directly to the heart through the electrode means, a delay means for ensuring that a time delay exists between the sensing of the initial heart malfunction and the discharge of the storage means into the heart, and a means for inhibiting the discharge of the storage means whenever conditions of normal heart activity are sensed.

Claim 6 provides for the device as recited in Claim 5 where at least one of the electrode means is adapted to be positioned within the heart.

Claim 1 of the '536 patent provides for a method for cardioverting a malfunctioning heart with a single intravascular catheter carrying first and second spaced electrodes for delivering to the heart electrical energy to cardiovert the heart. The claim further provides a method comprising the steps of positioning the single intravascular catheter into association with the heart, with the first electrode located within the heart chamber to be cardioverted, and the second electrode located outside the heart chamber, sensing heart activity and delivering energy to the heart across the first and second electrodes when a malfunction susceptible to conversion by electrical shock is sensed.

During the re-examination of the '757 patent, the PTO considered 17 patents and 21 publications as prior art, including the Berkovits patent, Trial Exhibit 1304, the Satinsky article, Trial Exhibit 1164, and the Hopps article, Trial Exhibit 1172.

During the re-examination of the '536 patent, the PTO considered 11 patents and 13 publications as prior art, including the Hopps article.

All the elements of the invention patented in the '757 patent are not found in any single prior art patent, publication or device relied on by Medtronic.

All the elements of the invention patented in Claim 1 of the '536 patent are not found in any single prior art patent, publication or device relied on by Medtronic.

Trial Exhibit 1188, referred to as the Cotelec document, was disseminated or otherwise made available in a foreign country to persons of ordinary skill in the art of defibrillation prior to February 19, 1969.

The jury concluded, and I concur, that the Cotelec document was a printed publication in a foreign country prior to February 9, 1969.

The jury concluded, and I concur, that Medtronic failed to prove by clear and convincing evidence that every element of

Claim 4 of the '757 patent is found in the Cotelec document.

The Cotelec document illustrates an automatic defibrillator, a method of continually sensing the heart with a discriminatory means, a delay and inhibiting means and a means to cardiovert a malfunctioning heart.

The device described in the Cotelec document could deliver only one shock and then had to be manually restarted.

A physician had to be in attendance during the use of the Cotelec device.

The Cotelec publication does not describe a storage means for electrical energy.

The Cotelec publication contemplated use of AC current with the unit obtaining its current from a wall socket.

The Cotelec publication does not describe internal electrodes, but states that they should be applied to the cardiac muscle.

The Cotelec reference to internal electrodes was in the context of open-heart defibrillation.

The Berkovits patent, the Stephenson article, which is Trial Exhibit 1167, and the Satinsky article reveal storage means in a defibrillator.

The Satinsky article does not specify that electrodes must be placed directly on the heart or that energy is applied directly to the heart.

The Berkovits patent did not provide for the possibility of inhibition, but discloses applying a defibrillation shock directly to the heart to cause cardioversion.

The Iwa Moto article, Trial Exhibit 1227, discloses application of a defibrillation shock directly to the heart to cause cardioversion.

The Hopps cardioverter disclosed in the Hopps reference was not automatic, did not have a means for continually sensing the function of the heart, did not have a means for discriminating between normal and abnormal heart activity, and did not use an energy storage means.

The Hopps reference discloses internal positioning of electrodes.

The experiments in defibrillation conducted by Dr. Schuder during late 1969 and January and February of 1970, were not disclosed in a publication until June of 1970.

Dr. Schuder implanted a defibrillator in a dog on January 16, 1970.

The electrodes used in Dr. Schuder's defibrillator were applied on the external rib cage, and thus were separated from the heart.

All of the prior art references relied on by Medtronic at trial lack one or more of the elements of each of the claims in issue of the '757 and '536.

The patented invention as a whole was not taught by the prior art relied on by Medtronic.

A person of ordinary skill in the art is one who is knowledgeable in the field specified, who is familiar with the literature, and who understands the technical merits.

The application for the '757 patent was first filed on February 9, 1970, by Ronald Cohn, Dr. Mirowski's counsel. The application was later filed as a reissue application on February 25, 1972. And the '757 patent was issued on September 11, 1973.

The application for the '536 patent was originally filed by Medtronic counsel on behalf of Dr. Mirowski on March 15th, 1971, as patent application No. 124,326, which has been referred to as 326 application, but that was later abandoned. The application for the '536 patent was filed on September 19, 1973, by counsel for Dr. Mirowski as a continuation-in-part of the 326 application. The '536 patent was issued on March 9, 1976.

Medtronic decided to discontinue its defibrillation program and, in notices dated September 14, 1972, canceled its relationship with Dr. Mirowski and Dr. Morton Mower, a collaborator of Dr. Mirowski's.

By an instrument dated November 14, 1972, Medtronic assigned the patent rights under the '757 patent and the 326 applications back to Dr. Mirowski. Dr. Mirowski then executed

a power of attorney to his counsel, Ronald Cohn, Esquire, on November 20th, 1972. Mr. Cohn thereafter prosecuted the '757 and 326 applications on behalf of Drs. Mirowski and Mower.

Examiner Kamm handled the patent applications for both the '757 and '536 patents. He also conducted the re-examination of both patents in suit. These applications and re-examination proceedings were handled contemporaneously for both patents by Examiner Kamm.

On May 2nd, 1972, Examiner Kamm performed a prior art search in connection with the 326 application.

Examiner Kamm found the Hopps article and cited it in a letter of August 3rd, 1972, to Medtronic's counsel.

Medtronic had a copy of the Hopps reference in 1972 at the time of the prosecution of the '757 patent.

Medtronic's counsel failed to cite the Hopps article to Examiner Kamm during their prosecution of the '757 patent.

In letters of September 29th, 1972, and October 12th, 1972, to Ronald Cohn, Medtronic stated that its cancellation of the defibrillation program was based, in part, on its belief that the Hopps article invalidated the '757 patent because it disclosed the use of an electrode positioned within the heart for defibrillation.

On November 28th, 1972, Ronald Cohn filed a letter with the PTO with regard to the '757 application citing the Hopps reference and other articles and indicating that "none of these references is any more pertinent than those already cited in connection with the prosecution of this application."

Mr. Cohn did not submit a copy of the Hopps reference to Examiner Kamm in connection with the '757 patent application.

In his testimony, during the course of this litigation, Dr. Hopps stated that his article taught that larger dogs or larger hearts could not be defibrillated by the technique taught in his article.

Dr. Hopps himself concluded that shocks applied through an intracardiac catheter were not effective in cardiac defibril-

lation and that delivering large energies through a catheter dispersive electrode arrangement would not be successful for larger, that is human hearts.

Examiner Kamm had a copy of the Hopps reference during the re-examination of the '757 patent.

All the claims of the '757 patent were initially rejected during the re-examination on the basis of Hopps' teaching of direct application of cardioverting energy to the heart.

Dr. Mower was subsequently interviewed by Examiner Kamm. This was during the re-examination of the '757 patent and Dr. Mower at that time stated that some of the successful defibrillations reported by Hopps might have been the result of spontaneous defibrillation in small dogs.

Dr. Mower, in an affidavit to Examiner Kamm, stated that Hopps recognized a relationship between the size of the dog and the ability to close-chest defibrillate. Dr. Mower also stated that the Hopps experiments were totally unsuccessful with regard to larger dogs having heart sizes closer to that of human beings.

Dr. Mower did state to Examiner Kamm to the Hopps reference indicated that closed-chest defibrillation with a catheter electrode was possible in small dogs.

Dr. Mower did not disclose to Examiner Kamm his association with Dr. Mirowski or his interest in this litigation.

Dr. Mower testified at trial that he believed Examiner Kamm knew of his relationship with Dr. Mirowski because he and Dr. Mirowski were named as inventors of the '536 patent.

In his testimony at trial, Dr. Mower expressed his belief that small dogs occasionally spontaneously defibrillate. Dr. Mower's representations to Examiner Kamm were made on the basis of this belief which was a result of his own experience and that of other researchers.

In a 1974 publication, of which Dr. Mower was listed as one of the authors, there is a statement that spontaneous defibrillation never occurs in adult dogs, sheep or in man.

Dr. Mower did not reveal to Examiner Kamm his 1974

publication, the references upon which he based his belief that small dogs spontaneously defibrillate, or references which contradict that belief.

Both Mr. Cohn and Dr. Mower believed that the Hopps reference did not invalidate the '757 patent application.

At the time Mr. Cohn could reasonably have concluded that Examiner Kamm had a copy of the Hopps reference and was aware of it, since it was Examiner Kamm who first cited the reference to Medtronic's counsel in 1972 and the two patent applications and re-examinations were being processed by Examiner Kamm at the same time.

Neither Mr. Cohn nor Dr. Mower intended to withhold the Hopps reference from Examiner Kamm or to mislead him with regard to its teachings and the patentability of the '757 claim.

Dr. Mower's favor to disclose his relationship with Dr. Mirowski to Examiner Kamm during the re-examination of the '757 patent was the result of his good faith belief that Examiner Kamm knew of his collaboration with Dr. Mirowski on the '536 patent.

Dr. Mower's failure to reveal his interest in this litigation was an error in judgment, not result of any intent to deceive Examiner Kamm.

Dr. Mower was a credible witness at trial, entitled to belief, and, in fact, I did believe him.

During the re-examination of the '757 patent, Examiner Kamm relied on Dr. Mower's affidavit in concluding that the Hopps article should not be considered a clear teaching for catheter defibrillation and in confirming the claim of the '757 patent with one amendment to Claim 4.

The 326 patent application, filed March 15, 1971, discloses a single intravascular catheter electrode system with a suggested inter-electrode spacing of 4 to 4.5 inches when the catheter is used for ventricular defibrillation.

The 326 patent application indicates that the inter-electrode spacing of 4 to 4.5 inches is a "good average" and that the required

spacing of electrodes "will be slightly different from one patient to the next."

The 326 patent application also indicates that the intravascular catheter electrode system disclosed in the patent application can be used in an atrial electrode arrangement in addition to its use in treating ventricular tachycardia and fibrillation.

The second application for the '536 patent, which was filed on September 19th, 1973, as a continuation-in-part of the 326 application discloses a single intravascular electrode system with inter-electrode spacing of at least two and a half inches to three inches apart.

During the prosecution of the '536 patent application, Drs. Mirowski and Mower, through their counsel, Ronald Cohn, represented to the PTO that the space electrodes were defined in the claims of the patent application as "either being at least about two and one half inches apart, or adapted to reside in specific regions in such a manner which clearly defines an electrode spacing of on" - that's what it says - "the same order."

During the prosecution of the '536 patent application, Drs. Mirowski and Mower, through their counsel, Ronald Cohn, represented to the PTO that the inter-electrode spacing of the '536 patent application was not taught by any references of the record or any prior art.

The claims of the 536 patent disclose inter-electrode spacing of two and a half inches, three to five inches, four and four and a half inches and two and a half to four inches apart.

Drs. Mirowski and Mower published a certain article referred to as an abstract in April 1972 in a publication called Clinical Research. This abstract described a defibrillation system that uses a single intravascular catheter with two electrodes spaced by three and a half to 4.7 inches.

Neither Dr. Mower nor Dr. Mirowski disclosed a publication of the abstract to Examiner Kamm.

Dr. Mower testified at trial that the two and a half inch inter-electrode spacing in the '536 patent corresponded to the size of the right atrium and that such spacing in the catheter's use

in an atrial electrode arrangement was disclosed in the 326 patent application.

Dr. Mower testified at trial that he believed that a disclosure of inter-electrode spacing of two to two and a half inches was inherent in the September 19, 1971 application for the '536 patent.

Dr. Mower testified that he considered the abstract published in 1972 to have been published after the application for the '536 patent and the disclosure in that application of inter-electrode spacing.

During the prosecution of the '536 patent application, Drs. Mirowski and Mower disclosed to the PTO the Charms patent, Patent No. 3,738,370. The Charms reference was cited to Examiner Kamm as being "of interest only."

The Charms patent contains electrode spacing disclosures which are interchangeable with the spacing disclosures contained in the abstract published by Drs. Mirowski and Mower.

Medtronic submitted the withheld abstract to Examiner Kamm during the re-examination of the '536 patent.

Examiner Kamm determined that the abstract was "pertinent" to the claim limitations of inter-electrode spacing in the '536 patent, but based his rejection of certain claims on the Charms reference.

During the re-examination of the '536 patent, Examiner Kamm determined that, because of spacing claims of the '536 application were not described in the 326 application, the spacing claims of the '536 application were entitled only to the '536 application filing date rather than the 326 patent application filing date.

Neither Dr. Mirowski nor Dr. Mower withheld the abstract in an effort to mislead or deceive Examiner Kamm during the prosecution of the '536 patent. Indeed they revealed the existence of the Charms patented.

Prior to the invention disclosed in the '757 and '536, a number of persons skilled in the art of defibrillation were attempting to invent a defibrillator such as the patented invention.

The devices of the patents filled a long-felt need for such a treatment for ventricular tachycardia and ventricular fibrillation.

The development of its defibrillator under the '757 and '536 patents had been the reason for CPI's recent profitability and growth.

The success and acceptance of CPI's defibrillators has also improved sales of CPI's pacemakers.

The patented invention has been recognized in the medical field as a life-saving device.

Dr. Mirowski has been recognized as a pioneer in the field of defibrillation.

The '757 patent is a very basic patent entitled to broad protection.

I granted Lilly's motion for a directed verdict with regard to the validity of the '536 patent and the infringement of Claim 1 of the '536 patent by Medtronic's devices.

The jury decided model 7210 infringes Claims 1 through 6 of the '757 patent. I also conclude that model 7210 infringes these claims of the '757 patent.

The jury decided that Model 7215 infringes Claim 5 of the '757 patent. I also conclude that Model 7215 infringes Claim 5 of the '757 patent.

The jury decided that Medtronic's infringement of the patents in suit was willful, and I concur.

For purposes of Lilly's motion for an injunction, I find that model 7210 contains all the elements of Claim 1 of the '757 patent, including a means for continually sensing the function of the heart.

As commonly understood, the word "continually" means regularly and without any substantial interruption of sequence. It does not mean without interruption whatsoever.

Model 7210 contains the element of Claim 2 of the '757 patent in that it contains a delay means.

Model 7210 contains Claim 3 of the '757 patent in that it contains a means for inhibiting discharge of the storage means under conditions of normal heart activity. As commonly understood, the word "inhibit" means to restrain or hold in check.

Model 7210 incorporates the elements of Claim 4 of the '757 patent in that it performs the method described in Claim 4.

Model 7210 contains the elements of Claim 5 of the '757 patent.

Model 7210 contains the elements of Claim 6 of the '757 patent in that the 7210 provides that at least one electrode is adapted to be positioned within the heart.

Model 7215 incorporates the elements of Claim 4 of the '757 patent in that when implanted, it performs a method described in Claim 4.

Model 7215, however, does not infringe Claim 4 since no implants of the 7215 were made in the United States.

Model 7215 contains the elements of Claim 5 of the '757 patent.

Model 7210 and 7215 perform substantially the same function as the patented invention in substantially the same way with substantially the same result as the patented invention.

Medtronic has planned to manufacture a 7216 which is similar to Model 7215, but can deliver a greater amount of electrical energy.

With its models 7210 and 7215, Medtronic plans to enter and eventually dominate the market for tachycardia and defibrillator devices in the United States. As I previously stated, Medtronic is an industry leader in the field of medical devices, including those that are used to treat heart problems.

The '757 patent was originally to expire on October 26, 1988, but a two-year extension was granted by the PTO pursuant to 35 United States Code, Section 156.

The '757 patent will, thus, expire on October 26, 1990.

The '536 patent will expire on September 19, 1993.

Lilly and CPI will be irreparably harmed if Medtronic is not enjoined from further infringement of Lilly's patents.

CPI has invested over \$20 million in development of its devices under the patents-in-suit.

Denial of an injunction would allow Medtronic to use its defibrillation devices and its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation.

Future monetary damages could not adequately compensate Lilly for its right to exclude Medtronic under the patents.

While the public interest is unquestionably advanced through the marketing of potentially lifesaving devices such as Medtronic's, Congress has determined it better for the nation in the long run to afford the inventors of novel, useful and non-obvious products short-term exclusivity on such products rather than to permit free competition in the goods. Congress has not seen fit to differentiate between what might be referred to as lifesaving devices and those of a more trivial or less important nature.

The public interest is served by granting injunctions to effectuate patent rights.

Lilly and CPI are continuing the advanced development of their defibrillation devices and making such devices available to the public. There was no inequitable conduct attributable to the plaintiff.

I reach the following conclusions of law. Jurisdiction in this case is based on 28 United States Code, Section 1338.

Venue and personal jurisdiction are proper and are not contested, as stipulated by the parties. This Court has jurisdiction over the parties and subject matter of this suit.

Lilly has proved by a preponderance of the evidence that Medtronic's model 7210 infringes the '757 and '536 patents.

Lilly has proved by a preponderance of the evidence that Medtronic's Model 7215 infringes the '757 and '536 patents.

Lilly has proved by clear and convincing evidence, and the

jury has decided, that Medtronic's infringement of the '757 and '536 patents was willful.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that every single element of the invention claimed by the '757 patent is found in one single prior art patent, publication or device.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that every single element of the invention claimed by Claim 1 of the '536 patent is found in one single prior art patent, publication or device.

On the basis of the prior art presented at trial, Medtronic has failed to prove by clear and convincing evidence that the differences between the subject matter claimed and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art in question.

On the basis of the evidence presented at trial, Medtronic has failed to prove by clear and convincing evidence that each of the patents of Dr. Mirowski was procured by inequitable conduct before the PTO, such as to render the patents unenforceable.

On the basis of the evidence presented at trial, Medtronic has failed to prove by clear and convincing evidence that the description of the inventions of the '757 patent and Claim 1 of the '536 patent, and of the manner and process of making and using them, is such as to fail to enable a person with ordinary skill in the art to make and use the inventions.

A patent gives the owner or his licensee the right to exclude all others from the use, manufacture or sale of devices which infringe his patent.

Courts having jurisdiction over patent cases "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent on such terms as the Court deems reasonable."

During an extension of the term of a patent which claims a product, the rights derived from the patent are "limited to any

use approved for the approved product before the expiration of the term of the patent under the provisions of law under which the applicable regulatory review occurred."

During an extension of the term of a patent which claims a method of using a product, the rights derived from the patent are "limited to any use claimed by the patent and approved for the approved product before the expiration of the term of the patent under the provisions of law under which the applicable regulatory review occurred."

The last two references were to 35 United States Code, Sections 156(b)(1) and 156(b)(2).

35 United States Code section 156(b)(1) and 35 United States Code Section 156(b)(2) do not preclude the issuing of injunctive relief in this case since Medtronic is only enjoined from any uses for which Lilly's products and methods for using a product had been approved prior to the expiration of the original patent terms.

The grant or denial of an injunction is within the sound discretion of this Court and of course depend upon the facts in each case, and specifically, here on the facts in this case.

Although a district court has discretion as to whether to enter an injunction or not, the exercise of that discretion cannot be arbitrary.

The grant of an injunction in this case would not be arbitrary.

While the grant of injunctive authority under 35 United States Code, Section 2283 is clearly in discretionary terms, injunctive relief against an infringer is the norm in a patent case, since monetary damages are often inadequate for continued infringement.

While damages are awarded as compensation for past infringement, an injunction is designed to prevent future infringement of a patent.

The jury determined damages for infringement based upon an assumed license for the period 1983 to March of 1988. An injunction, therefore, is appropriate to enjoin any future unlicensed and infringing manufactures, uses or sales by Medtronic.

The fact that Medtronic has ceased production of model 7210 does not prevent issuance of an injunction against any further infringement.

Any continued manufacture, use or sale of Medtronic's 7210 and its associated leads would infringe the '757 and '536 patents.

Any continued manufacture, use or sale of Medtronic's 7215 and its associated leads would infringe the '757 and could infringe the '536 patent.

Development of Medtronic's model 7216, since it is similar in design and function to the 7215, would infringe the '757 patent.

And accordingly, I will issue an injunction order.

APPENDIX G
IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN
DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

MEMORANDUM AND ORDER

DITTER, J.

April 21, 1988

Plaintiff Eli Lilly and Company brought this suit against defendant Medtronic, Inc. alleging infringement by Medtronic of two United States patents, No. Re. 27,757, reexamined and issued as Bl Re. 27,757 (the 757 patent) and No. 3,942,536, reexamined and issued as Bl 3,942,536 (the 536 patent). At the close of Medtronic's case, with the agreement of the parties, I granted Lilly's motion for a directed verdict with regard to the validity of the 536 patent and its infringement by Medtronic's Model 7210 and its associated leads. The jury subsequently returned a verdict in favor of Lilly, having found Medtronic's devices to infringe the claims of the 757 patent. The jury also decided that Medtronic's infringement of the 757 and 536 patents was willful. The parties agreed to submit for my determination the issue as to whether the alleged inequitable conduct of the patents' inventors,¹ Dr. Michel Mirowski and Dr. Morton Mower, before the United States Patent and Trademark Office (PTO) during the prosecution and reexamination of the patents-in-suit renders both patents unenforceable. For the reasons which follow and based upon the findings of fact and conclusions of law made

¹ Dr. Michel Mirowski is the inventor of the 757 patent. Dr. Mirowski, Dr. Morton Mower, and Rollin H. Denniston, a Medtronic engineer, are listed as the inventors of the 536 patent.

of record on April 15, 1988, I conclude that Medtronic has failed to prove by clear and convincing evidence that the patents-in-suit are unenforceable because of inequitable conduct on the part of their inventors. Since I find that both patents-in-suit are enforceable, I will direct that judgment be entered in favor of Lilly and against Medtronic in accordance with the jury's verdict.

Medtronic contends that Drs. Mirowski and Mower were guilty of certain instances of inequitable conduct with regard to each of the patents in suit. I will discuss each of Medtronic's claims.

A. The 757 Patent

1. Conduct During Initial Prosecution of the 757 Patent

Medtronic argues that, in 1972, during the prosecution of the 757 patent, Dr. Mirowski and his counsel, Ronald Cohn, Esq., were guilty of inequitable conduct because they failed to disclose as prior art to Examiner William E. Kamm, the patent examiner who was reviewing the 757 patent application,² an article published in 1954, by Dr. John Hopps. Medtronic contends that the Hopps article renders the 757 patent invalid because it specifically teaches the use of an electrode positioned within the heart for defibrillation, one of the features of the claims of the 757 patent.

The patent application for the 757 patent was first filed on February 9, 1970, by Ronald Cohn, Dr. Mirowski's counsel. Medtronic counsel later assumed the prosecution of the 757 patent on behalf of Dr. Mirowski. A reissue application for the 757 patent was filed on February 25, 1972. The application for the 536 patent was filed by Medtronic counsel on behalf of Dr. Mirowski on March 15, 1971, as patent application Serial No. 124,326 (the 326 application). At the time, Medtronic was undertaking prosecution of both Dr. Mirowski's patent applications under an agreement with Dr. Mirowski to develop the invention of the 757 patent application, an automatic defibrillator. Medtronic

² Examiner Kamm handled both the application for the 757 patent and the application for the 536 patent. He also reexamined both the patents-in-suit.

subsequently decided to discontinue its defibrillation program and its relationship with Dr. Mirowski and assigned the patent rights under the applications back to Dr. Mirowski. Dr. Mirowski's counsel, Mr. Cohn, thereupon undertook prosecution of the patent applications on behalf of Dr. Mirowski.

On May 2, 1972, Examiner Kamm performed a prior art search in connection with the 326 application and found the Hopps article which he cited to Medtronic counsel in a letter of August 3, 1972. Sometime prior to August 7, 1972, however, Medtronic had a copy of the Hopps reference in its corporate library, although Medtronic disputes whether the Medtronic counsel prosecuting the 757 patent were aware of it. In any event, after being informed of the Hopps article by Examiner Kamm with regard to the 326 application, Medtronic failed to cite the article to Kamm with regard to the 757 patent application despite its responsibility under the agreement with Dr. Mirowski for prosecution of the 757 application. Having cancelled its relationship with Dr. Mirowski by a notice dated September 14, 1972, Medtronic, in letters of September 29, 1972, and October 12, 1972, to Mr. Cohn stated that its cancellation of its defibrillation program was based, in part, on its belief that the Hopps article invalidated the 757 patent because it disclosed the use of an electrode positioned within the heart for defibrillation.³

After Medtronic assigned the patent rights back to Dr.

³ The September 29, 1972, letter states:

We have reviewed the defibrillator program and as indicated in our cancellation notices dated September 14, 1971 (sic) to Drs. Mirowski and Mower, we have decided to discontinue the program. Therefore, we have undertaken and completed a comprehensive study of the issued patents and pending applications involved in the program.

Trial Exhibit 269 (emphasis added). Lilly argues that the inference from the timing of the letters and the language of the September 29, 1972, letter is that Medtronic decided to cancel its defibrillator program and relationship with Drs. Mirowski and Mower and then decided to use the Hopps reference as justification for doing so. Medtronic contends that the Hopps reference was "The straw that broke the camel's back," leading to cancellation of Medtronic's relationship with both doctors. Trial Transcript, Testimony of Donald Stone, Day 8, p. 153).

Mirowski in an assignment dated November 14, 1972, Dr. Mirowski executed a power of attorney to Ronald Cohn on November 20, 1972. Mr. Cohn thereupon prosecuted the 757 and 326 applications on behalf of Drs. Mirowski and Mower. In a letter of November 28, 1972, to Examiner Kamm regarding the 757 application, Mr. Cohn cited the Hopps reference and other articles saying that "none of these references is any more pertinent than those already cited in connection with the prosecution of this application." Mr. Cohn did not submit a copy of the Hopps reference to Examiner Kamm.

2. Conduct During the Reexamination of the 757 Patent

Medtronic alleges certain statements made by Dr. Mower during the reexamination of the 757 patent with regard to the teachings of the Hopps article and the possibility of spontaneous defibrillation in small dogs constituted inequitable conduct. Medtronic also alleges that Dr. Mower intentionally withheld certain publications which contradict his statements to Examiner Kamm about spontaneous defibrillation in small dogs and the success of the Hopps experiments. Finally, Medtronic alleges that Dr. Mower intentionally withheld from Examiner Kamm the fact of his professional relationship with Dr. Mirowski.

During the reexamination of the 757 and 536 patents initiated by Medtronic in connection with this litigation, Medtronic submitted a copy of the Hopps reference to Examiner Kamm. All of the claims of the 757 patent were initially rejected by Examiner Kamm on the basis of Hopps teaching of direct application of cardioverting energy to the heart.⁴ As part of the reexamination proceedings, Dr. Mower was interviewed by Examiner Kamm and submitted an affidavit concerning the Hopps article.

The Hopps reference discloses the findings of Dr. Hopps' attempts in 1954 to defibrillate a number of dogs. In the portion

⁴ Lilly contends, and the testimony of Medtronic's expert, Professor Samuel Sutton, supports the fact that claims of patents are routinely, initially rejected in reexamination only to be later allowed without modification.

of the reference entitled "Closed Chest Defibrillation", the first attempt discussed involved a "modification of the intracardiac catheter electrodes as they lay in various portions in the right atrium and right ventricle." Trial Exhibit 1172, p. 841. As the article explains,

"[i]n every case but one, fibrillation persisted about the apex, and it was impossible to reach this extremity of the ventricles with the shock. In each instance, there was an area of burnt tissue around the electrodes after three or four shock applications. The one exception was a ten-kilogram dog whose heart was defibrillated on the fifth attempt . . ."

Id. The ten-kilogram dog was one of the smallest dogs in Hopps' experiment. *Id.*

In Dr. Hopps' next experiment, "a single electrode catheter in the heart and a large dispersive electrode on the front of the chest, over the apex of the heart" was used. *Id.* at 841-43. As explained in the article, "the technique proved fairly satisfactory in five of the eleven dogs." *Id.* at 843. Two of the five successes, however, were discounted because "the first attempts to defibrillate were unsuccessful, and it was necessary to open the chest, massage, and defibrillate with conventional electrodes before performing further tests with atrium-chest electrodes. Subsequent defibrillations by this method did not constitute valid tests under closed chest conditions." *Id.* Thus, closed chest defibrillation was successful in only 3 of 11 dogs. Dr. Hopps' report concluded:

5. Shocks applied through an intracardiac catheter were not effective in cardiac defibrillation. It was impossible to arrest the ventricular muscle around the apex by this method.

6. With a single intracardiac electrode and a dispersive electrode on the chest over the heart, closed-chest defibrillation was possible in smaller dogs. As in open-chest technique, there appears to be a relationship between the size of the dog and the ability to defibrillate.

Id.

Dr. Mower's affidavit to Examiner Kamm stated that the first closed chest technique was a failure and discussed this technique. Trial Exhibit 1173, para. 5-6. Dr. Mower noted that the second technique was reported as "fairly satisfactory" in five of the eleven dogs that were tested. *Id.* at para. 8. Dr. Mower explained that two of the five successes were discounted by Hopps and, thus, that "only three of the eleven dogs were apparently defibrillated in the manner intended." *Id.* at para. 7-8. Dr. Mower then noted that the three dogs that were defibrillated had weights lower than those dogs that could not be defibrillated. *Id.* at para. 9. Dr. Mower indicated in his affidavit that Hopps himself reached a similar conclusion that "there appeared to be a definite relationship between the size of the dog and our ability to defibrillate . . . [w]ith a larger dog, the greater the size of heart and increased current path undoubtedly contribute to the difficulty of defibrillation." *Id.* at para. 9.

Dr. Mower concluded his affidavit to Examiner Kamm by explaining that the Hopps reference would teach a person of ordinary skill in the art "that delivering large energies through a catheter/dispersive electrode arrangement would not be successful for larger hearts, such as human hearts." *Id.* at para. 13. Dr. Mower explained his conclusion by stating, "I believe that Hopps et al recognized this when they concluded, at page 848, that closed-chest defibrillation with a catheter electrode and dispersive electrode was possible in smaller dogs, in view of their further conclusion that there appears to be a relationship between the size of the dog and the ability to defibrillate (sic) (p. 848)." *Id.* Dr. Mower further concluded in his affidavit that "[t]he Hopps et al experiments were totally unsuccessful for larger dogs having heart sizes that would be closer to the size of a human heart. As such, one would be convinced by the Hopps et al teaching that the human heart would similarly be unsuccessfully treated." *Id.*

In his affidavit, Dr. Mower also stated that the dogs that Hopps reported as "successes" might have spontaneously defibrillated. Dr. Mower explained:

"[I]t is possible that the dogs may have spontaneously defibrillated . . . It is well known that smaller animals frequently spontaneously defibrillate. Hopps

et al themselves state, at page 840, that "[i]n human beings, as in most of the larger animals, it [fibrillation] is usually not reversible spontaneously," thus implying what is generally known, i.e., that small animals can defibrillate spontaneously. Thus, I cannot be certain that the return to normal heart rhythm of the three small dogs resulted from the energy that was applied via the catheter dispersive electrode arrangement, and not the phenomenon of spontaneous defibrillation."

Id. at para. 11.

In his trial testimony, Dr. Hopps testified that his article taught those of ordinary skill in the art that larger dogs or larger hearts could not be defibrillated by the method discussed in his article. Trial Transcript, Testimony of Dr. John Hopps, Day 10, p. 160 (emphasis added). Dr. Mower, in his testimony at trial, maintained his belief that small dogs occasionally spontaneously defibrillate and that spontaneous defibrillation might have been the reason for the successes reported in the 3 dogs that were defibrillated. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 68, P. 72, p. 112-14.

Medtronic further contends that Dr. Mower intentionally withheld from Examiner Kamm a 1974 publication of his which purportedly contradicts his statements to Examiner Kamm regarding spontaneous defibrillation.⁵ Dr. Mower's publication confirms that ventricular fibrillation can be spontaneously reversed in small animals such as frogs, turtles, and cats. The article, however, also includes a statement to the effect that spontaneous defibrillation "has never been observed in over 200

⁵ Medtronic also contends that Dr. Mower should have disclosed certain other publications including the Wiggers and Garrey references. The Wiggers reference states that, in the hearts of larger animals, fibrillation is irrevocable and notes that in over 400 cases of fibrillation in dogs, only a single recovery was witnessed. Trial Exhibit 1406, p. 399. The Garrey reference states that the ventricles of dogs do not usually recover spontaneously from fibrillation, although they do so in rare instances. Trial Exhibit 1174, p. 397.

dogs of the body weight range described in the present experiments."⁶ Trial Exhibit 1178, p. 860. At trial, Dr. Mower explained that the statement was "the experience of two of our coauthors. It certainly wasn't my own experience. I had seen spontaneous defibrillation many times and the literature amply supported the fact that it occurs." Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 72.

To sustain the defense of inequitable conduct, Medtronic must prove two things by clear and convincing evidence: 1) that Drs. Mirowski or Mower or their counsel misrepresented or failed to disclose material information to the PTO in the prosecution and reexamination of the patents-in-suit, and 2) that such misrepresentation or omission was intentional or the result of gross negligence. *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1094 (Fed. Cir. 1987). See also *FMC Corp v. The Manitowoc Co.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) (one who alleges failure to disclose as inequitable conduct must offer clear and convincing proof of: 1) prior art or information that is material; 2) knowledge by the applicant of the materiality of the prior art or information; and 3) failure to disclose resulting from an intent to mislead the PTO).

The United States Court of Appeals for the Federal Circuit has stated that a trial court, in determining a claim of inequitable conduct, must balance the materiality of any withheld reference with the level of intent with which the prior art was withheld from the PTO. *FMC Corp.*, 835 F.2d at 1415; *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F.2d 292, 294 (Fed. Cir. 1986); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1363 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984). Having reviewed all the evidence with regard to Medtronic's specific allegations of inequitable conduct on the part of Dr. Mirowski and his counsel during the prosecution of the 757 patent, I can only conclude that Medtronic has failed to prove by clear and convincing evidence that Dr. Mirowski or his counsel was guilty

⁶ The dogs to which the 1974 article refers weighed 12-25 kilograms. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, p. 74. The dogs in the Hopps experiments weighed 10-22 kilograms. Trial Exhibit 1172, p. 843.

of any intentional or even grossly negligent withholding of any material information before the PTO.

First, the materiality of the Hopps article as a prior art reference is marginal at best. While the Hopps reference does disclose the use of an electrode positioned within the heart for defibrillation, the results of Dr. Hopps' experiments concluded that shocks applied through an intracardiac catheter were not effective in cardiac defibrillation and that delivering large energies through a catheter dispersive electrode arrangement would not be successful for larger, human hearts. In his testimony at trial, Dr. Hopps himself admitted that this was the conclusion of his experiments and the teaching of his reference. The few successes which Hopps achieved were with the smaller of the dogs involved in the experiments. If anything, the Hopps article teaches that one could not successfully defibrillate a heart the size of a human heart through the techniques disclosed in the reference. The failure of Medtronic counsel to cite the Hopps article to Examiner Kamm while they were prosecuting the 757 patent on behalf of Dr. Mirowski suggests that, at the time, Medtronic counsel, too, thought the article of little relevance. It certainly cannot be concluded that Examiner Kamm would have considered the Hopps reference important in deciding whether to allow the 757 patent application or that, but for the Hopps reference, he would not have allowed the patent to issue. See, e.g., *J.P. Stevens & Co., Inc. v. Lex Tex Ltd., Inc.*, 747 F.2 1553, 1559 (Fed. Cir. 1984) (setting forth standards in determining materiality of nondisclosed information). Contrary to Medtronic's contention, moreover, the fact that the claims of the 757 patent were initially rejected on the basis of Hopps during the reexamination of the 757 patent does not establish the materiality of the reference given the fact that all the claims were eventually allowed over the reference.

Even if there was some marginal materiality to the Hopps reference, Medtronic has made no showing that the failure of Dr. Mirowski or his counsel to provide a copy of the reference to Examiner Kamm was the result of an intent to mislead or deceive the PTO. See, e.g., *Akzo v. E.I. duPont de Nemours & Co.*, 810 F.2d 1148, 1152 (Fed. Cir. 1987). At the time Dr. Mirowski's counsel, Mr. Cohn, cited Hopps to Examiner Kamm, he stated

that it was no more pertinent than any other references previously cited to the PTO. Medtronic has produced no evidence showing that Mr. Cohn and Dr. Mirowski did not believe this to be the case at the time they made such a representation to the PTO. Medtronic has not shown that the failure to provide a copy of the Hopps article to Examiner Kamm was anything other than the result of Dr. Mirowski's and Mr. Cohn's good-faith belief that the reference was irrelevant to the 757 patent application. See, e.g., *Allen Archery, Inc.*, 819 F.2d at 1095 (failure to cite competitor's patent as prior art did not constitute inequitable conduct where applicant had good-faith belief that competitor's patent was not material to the prosecution of applicant's patent). Such a belief, moreover, given the testimony at trial, has been shown to be a reasonable one. See, e.g., *Argus Chemical Corp. v. Fibre Glass-Evercoat Co., Inc.*, 759 F.2d 10, 14-15 (Fed. Cir. 1985) (subjective good faith of counsel in not disclosing prior art does not negate inequitable conduct). See also *Laitram Corp.*, 785 F.2d at 294 (*Argus* did not hold that subjective good faith is never a defense to a claim of inequitable conduct; rather, materiality and intent must be balanced). It was, further, not unreasonable for Dr. Mirowski or Mr. Cohn to conclude that Examiner Kamm had a copy of the Hopps reference since it was Kamm who first cited the reference to Medtronic counsel in 1972. I conclude that the Hopps reference was not material, that neither Dr. Mirowski nor his counsel intentionally or negligently withheld the reference, and that their failure to provide a copy of Hopps to Examiner Kamm during the initial prosecution of the 757 patent did not amount to inequitable conduct.

Medtronic has also failed to sustain its burden with regard to its allegations of inequitable conduct on the part of Dr. Mower during the reexamination of the 757 patent. Medtronic has not shown how Dr. Mower's statements to Examiner Kamm intentionally mislead, or misrepresented, or withheld material information regarding the Hopps reference. Dr. Mower's affidavit to Examiner Kamm accurately reflected the success and failure of the Hopps experiments and indicated that Hopps had recognized a relationship between the size of the dog and the ability to defibrillate, with the difficulty increasing with the size of the dog. Dr. Mower represented to Examiner Kamm that Hopps did

not teach the successful application of defibrillating energy to larger, human hearts, a conclusion which Hopps himself confirmed at trial.

Medtronic's most strenuous contention, however, has been its claim that Dr. Mower intentionally misrepresented to Examiner Kamm the likelihood that some of the Hopps successes could be attributed to spontaneous defibrillation in small dogs. Dr. Mower stated in his affidavit that he could not be certain that the successes achieved by Hopps were not the result of spontaneous defibrillation. As he explained at trial, Dr. Mower suggested this possibility because he believed spontaneous defibrillation in small animals to be a frequent occurrence. I find no intent on Dr. Mower's part to mislead Examiner Kamm by failing to provide his 1974 article or the Wiggers or Garrey references which contradict his position on spontaneous defibrillation. As Dr. Mower testified at trial, he believed other literature, to which specific reference was made, fully supported his opinion that small animals can spontaneously defibrillate. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, pp. 112, 124-129.

Finally, Medtronic contends that Dr. Mower intentionally failed to disclose to Examiner Kamm his relationship with Dr. Mirowski. Medtronic argues that, because Dr. Mower has an agreement with Dr. Mirowski whereby Dr. Mower will receive a percentage of any recovery in this litigation, Dr. Mower should have disclosed this potential conflict to Examiner Kamm during the reexamination. At trial, Dr. Mower stated that he believed Examiner Kamm was aware of his close collaboration with Dr. Mirowski because both doctors were listed as inventors on the 536 patent and Examiner Kamm was handling both the 757 and 536 reexaminations.

I can find no inequitable conduct on the part of Dr. Mower in failing to disclose to Examiner Kamm his working relationship with Dr. Mirowski and his interest in this litigation. Dr. Mower testified that he believed Examiner Kamm knew of his association with Dr. Mirowski since both were listed as inventors of the 536 patent. This is a reasonable conclusion, moreover, since Examiner Kamm had handled both applications for the patents-in-suit as well as their reexamination. While Dr. Mower's interest in this litigation might have been of some relevance to Examiner Kamm

in evaluating Dr. Mower's statements during the reexamination, Dr. Mower's failure to disclose it is, at the most, an error of judgment which falls short of inequitable conduct. *See, e.g., Akzo*, 810 F.2d at 1152 (simple negligence or an error in judgment is never sufficient for a holding of inequitable conduct). An applicant need not disclose all information of pertinence to the PTO. The two controlling factors in determining a charge of inequitable conduct are the materiality of the withheld information and the intent of the actor. *Kimberly-Clark Corp. v. Johnson & Johnson Co.*, 745 F.2d 1437, 1454-55 (Fed. Cir. 1984) (citing *American Hoist*, 725 F.2d at 1362-64). Inequitable conduct is not established upon a showing that information of some materiality was not disclosed to the PTO. Rather, one must have intended to act inequitably. *FMC Corp.*, 835 F.2d at 1415. I cannot conclude, on the basis of the evidence presented at trial, that Dr. Mower had any such intent in not informing Examiner Kamm of his interest in this litigation.

B. The 536 Patent

With regard to the 536 patent, Medtronic alleges that the failure of Dr. Mower to disclose as prior art an article published by Drs. Mirowski and Mower in 1972 was inequitable conduct.

The 326 patent application, filed March 15, 1971, discloses a single intravascular catheter electrode system with a suggested inter-electrode spacing of 4 to 4 1/2 inches when the catheter is used for ventricular defibrillation. Trial Exhibit 733, p. 16. The second application for the 536 patent, which was filed on September 19, 1973, as a continuation in part of the 326 application, discloses a single intravascular electrode system with inter-electrode spacing of at least 2 1/2 to 3 inches. Trial Exhibit 628, p. 14. The claims of the 536 patent also disclose inter-electrode spacing ranging from 2 1/2 inches to 4 1/2 inches.

During the prosecution of the 536 patent application, in 1973, Drs. Mirowski and Mower represented to the PTO that the inter-electrode spacing of the 536 patent application was not taught by any references of record or any prior art. In April, 1972, Drs. Mirowski and Mower published a certain abstract in *Clinical Research* detailing a defibrillation system that uses a single intravascular catheter with two electrodes spaced by 3.5 to 4.7

inches. Trial Exhibit 1144. Medtronic contends that this abstract discloses a catheter system with electrode spacing within the claimed ranges of the 536 patent application. Medtronic thus argues that the 1972 abstract, having been published before the filing of the 536 patent application in 1973, is prior art which should have been disclosed to the PTO by Drs. Mirowski or Mower in the course of the prosecution of the 536 application.

The 326 patent application indicates that inter-electrode spacing of 4 to 4.5 inches is a "good average" and that the required spacing of the electrodes "will be slightly different from one patient to the next." Trial Exhibit 733, p. 16. The 326 application also indicates that the catheter electrode system disclosed in the patent application could be used in an atrial electrode arrangement in addition to its use in treating ventricular tachycardia and fibrillation. *Id.* at 9.

During the reexamination of the 536 patent, many of the new spacing claims of the patent were rejected as obvious in view of the Charms patent, Trial Exhibit 1319. This patent, which was cited to Examiner Kamm by Drs. Mirowski and Mower as "of interest only" during the prosecution of the 326 application, has a disclosure of spacing ranges interchangeable with those disclosed in the 1972 abstract. Examiner Kamm determined that, because the 1972 abstract recited spacing ranges not described in the 326 application, the spacing claims of the 536 patent were entitled only to the 536 patent continuation-in-part filing date of September 19, 1973, rather than the 326 application filing date of March 15, 1971.

Dr. Mower testified at trial that the 2 1/2 inch inter-electrode spacing in the 536 patent corresponded to the size of the right atrium and that such spacing in the catheter's use in an atrial electrode arrangement was disclosed in the 326 patent application. Trial Transcript, Testimony of Dr. Morton Mower, Day 11, pp. 100-101. Dr. Mower further testified that he believed a disclosure of inter-electrode spacing of 2 to 2 1/2 inches was inherent in the September 19, 1971, application for the 326 patent. *Id.* Finally, Dr. Mower also testified that he considered the abstract published in 1972 to have been published *after* the application for the 326 patent and the disclosure in that application of inter-electrode spacing. *Id.*

Given Examiner Kamm's findings during the reexamination regarding the spacing claims of the 536 patent, the materiality of the 1972 abstract is confirmed. Such a conclusion, however, does not establish that Dr. Mower was guilty of inequitable conduct in failing to cite the 1972 abstract to the PTO during the prosecution of the 536 patent. Medtronic has not shown by clear and convincing evidence that Dr. Mower intentionally concealed the abstract from Examiner Kamm or otherwise intentionally misled him with regard to the patentability of the spacing ranges claimed in 536 patent. Dr. Mower's trial testimony explained his belief that the 2 1/2 inch spacing range in the 536 patent was inherent in the 326 application and that the 1972 abstract was published after the filing date of the 326 application and was, thus, not prior art as to the 536 continuation-in-part application. Dr. Mower's failure to disclose the abstract, moreover, is made less significant given the fact that the Charms patent was cited by the inventors to Examiner Kamm during the prosecution of the 536 application. Even though it was cited as "of interest only", Charms, nonetheless, contains spacing claims identical to those in the abstract. Had Dr. Mower intended to conceal the spacing claims disclosed in the abstract, he certainly would not have disclosed the equally damaging Charms patent to Examiner Kamm. Balancing the materiality of the abstract against the lack of any showing by Medtronic of intent or gross negligence on the part of Dr. Mower, I must conclude that he is not guilty of any inequitable conduct before the PTO. *See, e.g., Akzo*, 810 F.2d at 1153 (although material misrepresentation was made to the PTO, patentee was not guilty of inequitable conduct where no showing was made of intent or gross negligence on the part of patentee). The 536 patent is, therefore, enforceable.

An appropriate order follows.

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN
DISTRICT OF PENNSYLVANIA

ELI LILLY AND COMPANY,
Plaintiff,

v.

CIVIL ACTION
No. 83-5393

MEDTRONIC, INC.,
Defendant.

ORDER

AND NOW, this 21st day of April, 1988, for the reasons stated in the accompanying memorandum, it is hereby ordered:

1. United States patents, No. Re. 27,757, reexamined and issued as Bl Re. 27,757, and No. 3,942,536, reexamined and issued as Bl 3,942,536, are valid and enforceable;

2. Judgment is hereby entered in favor of plaintiff Eli Lilly and Co. and against defendant Medtronic, Inc., in the amount of \$26,500,000, plus an additional royalty of \$166,000, totaling \$26,666,000.

BY THE COURT:

/S/ J. William Ditter, Jr.

APPENDIX H

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

88-1409

ELI LILLY AND COMPANY,
Plaintiff-Appellee,

v.

MEDTRONIC, INC.,
Defendant-Appellant.

ON MOTION

Before NEWMAN, BISSELL and MAYER, *Circuit Judges.*
NEWMAN, *Circuit Judge.*

O R D E R

Medtronic, Inc. (Medtronic) moves for a stay pending appeal of a permanent injunction entered by the United States District Court for the Eastern District of Pennsylvania. Eli Lilly and Company (Lilly) opposes the motion.

Lilly brought suit against Medtronic alleging infringement of two of Lilly's patents related to medical devices for automatically cardioverting or defibrillating potentially fatal abnormal heart rhythms. Judgment was entered in favor of Lilly on April 21, 1988. A separate order was entered on that day permanently enjoining Medtronic from manufacturing, using, or selling certain of its medical devices. The district court thereafter denied Medtronic's motion for a stay pending appeal on May 4, 1988. On June 6, 1988, Medtronic filed the instant motion for stay pending appeal.

Medtronic argues (1) that the appeal involves a substantial legal question of first impression, *i.e.*, whether the infringement exemption of 35 U.S.C. § 271(e)(1)* applies to medical devices, (2) that the public will be harmed if Medtronic's devices are not available, (3) that Lilly will not be harmed and, in any event, could be compensated through a reasonable royalty, and (4) that Medtronic will be harmed if clinical testing and Federal Drug Administration marketing approval are postponed.

Having reviewed Medtronic's motion and Lilly's opposition, we are not persuaded that Medtronic's motion should be granted. The district court firmly rejected Medtronic's legal argument and held that § 271(e)(1) applied only to drugs and not to medical devices. Medtronic alleges no other basis for likelihood of success on the merits. Further, Medtronic's allegations of harm, all challenged by Lilly, do not persuade us that the balance tips in Medtronic's favor.

Accordingly,

IT IS ORDERED THAT:

Medtronic's motion for stay pending appeal is denied.

FOR THE COURT

7/28/88
Date/S/ P. Newman
Pauline Newman
Circuit Judgecc: Philip S. Johnson, Esquire
Timothy J. Malloy, Esquire

* Section 271(e)(1) of 35 U.S.C. provides:

It shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

APPENDIX I

S 2860

March 16, 1989

CONGRESSIONAL RECORD -- SENATE

BY MR. DECONCINI:

S.622. A bill to amend title 35 of the United States Code to clarify the Drug Price Competition and Patent Term Restoration Act of 1984 with respect to medical devices, to promote increase competition and innovation in lifesaving medical technologies and to improve patient and physician access to advanced experimental therapeutical alternatives; to the Committee on the Judiciary.

MEDICAL TECHNOLOGY COMPETITIVENESS ACT

MR. DECONCINI. Mr. President, I rise today along with my colleagues Senators DURENBERGER, ADAMS, and GORTON to introduce the Medical Technology Competition Act of 1989. This bill clarifies the Drug Price Competition and Patent Term Restoration Act of 1984 with respect to medical devices; it promotes increased competition and innovation in life-saving medical technologies; and it improves the access of physicians and patients to advanced experimental therapeutical alternatives.

My bill addresses what has become a point of some controversy with Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984. This law authorized the extension of certain patents in order to restore the patent time lost due to the period of FDA regulatory review for the patented inventions; and it also provided an experimental use or research exemption from infringement under which competitors can test experimental products. That is, the law permits competitors to engage in non-commercial research and development during the term of a patent so that commercial competition can proceed as soon as the patent expires. The law reversed the holding of *Roche Products v. Bolar Pharmaceutical Co.*, 221 U.S.P.Q. 937 (1984) by means of 35 U.S.C. 271(e)(1), which provides

It shall not be an act of infringement to make, use, or sell a patent invention (other than a new animal

drug or veterinary biological product) * * * solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs.

The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medical devices and this must be clarified. The American Bar Association Section of Patent, Trademark and Copyright Law stated in its 1988 committee report:

In summary, the [ABA] subcommittee wishes to state its conviction that such an experimental or research exemption either does exist or should exist. Such a research exemption should apply to all products, not just to generic drugs.

My bill provides the necessary statutory clarification for medical devices and reaffirms the purpose behind the 1984 law—to balance the rights of patent holders—who were provided with the ability to secure patent extensions—with the public good of immediate increased competition once the patent expires.

Even more alarming than the evident legal unfairness with the state of the law at this point is its apparent effect of prohibiting physicians from conducting clinical evaluations of state-of-the-art experimental medical devices that are desperately needed to treat serious heart conditions. A number of well-respected physicians at this country's leading hospitals and medical institutions have told me of seriously ill patients in need of an experimental medical device that cannot be used because it infringes the patent of a device already on the market. These physicians are, in effect, being blocked from practicing medicine to the best of their ability. The patients are immediate losers in this situation. We should also realize that, to a degree, we all are losers—because technological innovation is hampered, because medical progress is slowed, and because free competition and the ability to experiment are obstructed.

It is not often that one has the opportunity to take an action that will have as great an impact on patients' lives as will the

passage of this bill. I am mindful of the rights of patent holders, and I value the need to protect intellectual property rights. This bill will not change the term of the patent. However, it will ensure that there is not a de facto extension which occurs when competitors are forced to wait until after the patent expires before even beginning the experimental use required for FDA approval.

While this issue came to my attention as a result of a current legal controversy, my motivation in introducing this bill is not to side with one patent holder over another, and it is not to choose one course of medical treatment or medical device over another. My purpose is to restore the proper balance in our patent laws and to do it as quickly as possible in light of the immediate patient care situation. I am pleased that several of my colleagues upon learning of the importance of this issue have joined me in sponsoring this legislation and I urge my other colleagues to support this much-needed legislation. Mr. President, I ask unanimous consent that the bill be printed in the RECORD following my statement.

There being no objection, the bill was ordered to be printed in the RECORD, as follows:

S.622

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Technology Competitiveness Act of 1989".

SEC. 2 INFRINGEMENT OF PATENT.

Section 271(e) of title 35, United States Code, is amended

(1) in paragraph (1) by inserting ", medical devices" before "or veterinary biological products";

(2) in paragraph (2) by -

(A) striking out "or" at the end of subparagraph

(A);

(B) adding "or" at the end of subparagraph (B);

(C) inserting between subparagraph (B) and the matter that follows such subparagraph, the following:

"(C) an application under section 515(c) of such Act (21 U.S.C. 360e(c)) for a medical device which is claimed in a patent or the use of which is claimed in a patent,"; and

(D) inserting ", medical device" before "or veterinary biological products"; and

(3) in paragraph (4) by inserting ", medical device" before "or veterinary biological product" each place it appears in subparagraphs (A), (B), and (C).

APPENDIX J

STATUTE INVOLVED

35 U.S.C. § 271(e)

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit-

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under Section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)-

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285. (Added September 24, 1984, Public Law 98-417, sec. 202, 98 Stat. 1603; Amended November 16, 1988, Public Law 100-670, sec. 201, 102 Stat. 3989.)

(2)

Supreme Court, U.S.

FILED

SEP 11 1989

JOSEPH F. SPANIOL, JR.
CLERK

No. 89-243

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**ON PETITION FOR A WRIT OF
CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE
FEDERAL CIRCUIT**

RESPONDENT'S BRIEF IN OPPOSITION

Philip S. Johnson

Counsel of Record

Gary H. Levin

Albert W. Preston

Henrik D. Parker

WOODCOCK WASHBURN KURTZ

MACKIEWICZ & NORRIS

One Liberty Place, 46th Floor

Philadelphia, PA 19103

215/568-3100

Counsel for Respondent

Of Counsel:

Ronald E. Lund

Joseph F. Breimayer

MEDTRONIC, INC.

7000 Central Avenue, NE

Minneapolis, Minnesota 55432

QUESTION PRESENTED

Whether the Federal Circuit erred in interpreting the phrase "patented invention" in the patent infringement exemption of 35 U.S.C. § 271(e)(1) to include not only drugs but also medical devices regulated by the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 *et seq.*).

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BRIEF FOR THE RESPONDENT IN
OPPOSITION

Respondent, Medtronic, Inc. ("Medtronic"), respectfully opposes the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari and requests that Lilly's petition be denied.¹

1. Pursuant to Rule 28.1 of the Rules of this Court, Medtronic states that it has no publicly owned parents, subsidiaries, or affiliates. Medtronic does hold a minority interest in Bio-Medicus, Inc. of Minnetonka, MN but does not regard it as an affiliate.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit is reported at 872 F.2d 402, and is reprinted in petitioner's appendix ("Pet.App."), at pp.1a-7a. The Court of Appeals denied a petition for panel rehearing on May 31, 1989 (Pet.App. 8a), and issued its judgment as a mandate on June 8, 1989 (Pet.App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing *in banc* on July 18, 1989 (Pet.App. 9a).

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania relating to the scope of 35 U.S.C. § 271(e)(1) is reported at 5 U.S.P.Q.2d 1760 (Pet.App. 15a). The district court also issued a memorandum decision granting a permanent injunction against respondent Medtronic (7 U.S.P.Q.2d 1439; Pet.App. 21a), and a memorandum decision directing that judgment be entered in favor of Petitioner Lilly (7 U.S.P.Q.2d 1447; Pet.App. 41a).

STATUTE INVOLVED

The relevant portions of 35 U.S.C. § 271 provide as follows:

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

* * *

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to

the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

STATEMENT OF THE CASE

Lilly brought this action in the United States District Court for the Eastern District of Pennsylvania (Philadelphia) charging Medtronic with infringement of two patents related to implantable medical devices (defibrillators) that automatically shock the heart to correct certain potentially fatal heart rhythms. (Pet.App. 1a-2a). The Medtronic activities charged with infringement were experimental in nature, conducted under the authority of FDA testing regulations. Such testing is a prerequisite to acquiring any FDA approval to commercialize a medical device.

Medical devices of the kind at issue here may not be commercialized in the U.S. prior to receipt of a pre-marketing approval ("PMA") from the FDA. Application for a PMA generally must be based on clinical experience gained in human trials, and even these trials may not be conducted in the U.S. without permission from the FDA. That permission, known as an Investigational Device Exemption ("IDE"), generally comes with strict controls on such aspects of the testing as the number of devices and the identity of hospitals, physicians, etc., to whom the devices can be supplied for the tests (Veale, Trial Test., Day 13, pp. 40-42).

During the pendency of the litigation, Lilly applied for and obtained a two-year extension of the only remaining patent in issue, U.S. Patent Re. 27,757 ("the '757 patent") (Trial Ex. 623).² According to the relevant

2. The other patent in suit, U.S. Patent 3,942,536, is no longer in issue since Medtronic discontinued its testing of the Model 7210 devices charged under that patent in 1985, and has no plans to resume testing of such devices.

statute (35 U.S.C. § 156), the right to, and length of, this extension was based upon the delay that Lilly claimed to have experienced while conducting the FDA-required IDE testing of its own devices (35 U.S.C. § 156(c) and (d); *see also* Trial Ex. 623). The extended '757 patent is now in its 18th year and will expire on October 26, 1990.

To date, Lilly's implantable defibrillators remain the only such devices approved by the FDA for commercialization in the United States (Strain, Trial Test., Day 3, p.60). During the two-year extension period of the '757 patent, Lilly is expected to sell 6,000 to 10,000 units and to collect \$100-160 million in sales.³

The Medtronic devices accused of infringement are experimental designs expected to lead to the next generation of implantable cardiac treatment devices. Medtronic's latest design, its PCD, is a combination pacer, cardioverter, defibrillator (Pet.App. 24a-25a). The PCD contains all of the features that Lilly's cardiology expert admitted at trial should be in the "ideal implantable device" (Luceri, Trial Test., Day 4, pp.166-67). Medtronic's units are designed to treat most cardiac disturbances painlessly, using low energy electrical impulses to treat all but the most severe conditions (Keimel, Trial Test., Day 7, pp.146-47; Klein, Trial Test., Day 9, pp.34-36, 45). In addition, since they incorporate standard bradycardia (slow heart beat) pacing therapies as well, their use by patients having multiple cardiac problems eliminates the need for implantation of a separate pacer.⁴

3. Lilly's systems sell for about \$16,000 each (Strain, Trial Test., Day 3, p.52). Lilly's projected sales for the extended term are reflected in Trial Ex. 532, as verified by Mr. Strain at trial, Day 3, pp.30-31.

4. The Lilly device, in contrast, treats abnormal heart rhythms by applying very high energy shocks through two electrodes connected directly to the heart (Pet.App. 26a). After experiencing these shocks, 85% of its patients live in "significant fear" of receiving

In the district court, Medtronic moved for a pre-trial ruling that its IDE testing was exempt from any charge of infringement under 35 U.S.C. § 271(e)(1). Judge Ditter denied the motion on December 4, 1987, ruling that the section 271(e)(1) exemption did not apply to medical devices, and entered an order precluding Medtronic's presentation of any evidence at trial concerning the exemption (Pet.App. 15a-20a).⁵

The case was subsequently tried to a jury on Lilly's charges that a total of 31 units, tested over a period of about five years, infringed claims of the patents in suit. The total value of the devices tested by Medtronic was less than \$415,000 (Trial Test., Day 18, p.29). Notwithstanding the limited nature of Medtronic's FDA-controlled testing, Lilly contended that the testing gave Medtronic a headstart towards an entry into the commercial marketplace.

Judgment was entered in favor of Lilly on April 21, 1988, including a damage award of a \$26.5 million "up-front" payment and a 40% running royalty (Pet.App. 55a). The injunction that was the subject of the interlocutory appeal to the Federal Circuit was entered on the same day, enjoining Medtronic from manufacturing its accused devices or testing them in humans or

additional shocks, 65% report reduced physical activity, 41% experience a reduction in social interaction, and 41% report sexual abstinence (Luceri, Trial Test., Day 4, pp.156-57). In the opinion of Lilly's own expert, Lilly's automatic implantable defibrillator is "Associated with multiple physical, social and psychological alterations" (*Id.*, at p.157). Moreover, unlike the Medtronic PCD, the Lilly device does not have standard pacing capability, and therefore, any Lilly patient who suffers from either continual or episodic bradycardia would require implantation of a separate pacer, with the additional cost involved and the attendant problems of uncoordinated electrical function between the two devices (*Id.*, at 157-159).

5. Section 271(e) was enacted by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("the 1984 Act"). This law also enacted 35 U.S.C. § 156, under which Lilly received its patent term extension.

animals, and from using data generated from any infringing manufacture, use, or sale of the devices (Injunction Order of April 21, 1988).

On March 29, 1989, the Federal Circuit reversed the district court's holding that section 271(e)(1) did not include medical devices, holding instead that Medtronic could proceed with testing of its devices if solely for purposes reasonably related to the development and submission of information to the FDA (Pet.App. 1a, 7a). The Federal Circuit also remanded the issue of whether Medtronic's earlier testing had been for those purposes (Pet.App. 7a).⁶

Lilly filed a petition for rehearing and suggestion for rehearing *in banc*. The panel denied rehearing on May 31, 1989 (Pet.App. 8a), and the Federal Circuit declined the suggestion for rehearing *in banc* on July 18, 1989 (Pet.App. 9a), with Judge Newman dissenting. The Federal Circuit's mandate issued, after denial of the rehearing, on June 8, 1989, and upon receipt of the mandate, the district court modified its injunction to permit Medtronic to proceed with its IDE testing (Order of June 28, 1989). On July 21, 1989, Lilly filed in this Court an application for an order directing the Federal Circuit to recall and stay its mandate pending the filing of, and final action on, a petition for writ of certiorari. That application was denied by Justice White on July 24, 1989.

Lilly now seeks this Court's review of the Federal Circuit's interlocutory interpretation of the principal patent infringement statute, 35 U.S.C. § 271.

REASONS FOR DENYING CERTIORARI

The decision below is nothing more than an ordinary interpretation of the patent laws by the specialized

6. This application of the Federal Circuit's decision, as well as the resolution of numerous post-trial motions, are currently before the district court. Accordingly, the judgment entered on April 21, 1988, is not final.

appellate court established by Congress for that purpose. The decision is in accord with the plain language of the statute, its legislative history, and the congressional policy behind it. Petitioner's arguments regarding the construction of the statute merely restate positions that a panel of the Federal Circuit unanimously rejected, and that the Federal Circuit declined to rehear *in banc*.⁷

Petitioner contends (Pet. 19) that the decision will slow the development and production of new medical devices by diverting profits from the patentee to competitors who conduct experimental FDA testing. Petitioner's argument erroneously assumes that the courts will give the exemption an overbroad construction and that the FDA itself will provide no effective check against abuse. As yet, however, the record contains no evidence that petitioner's assumptions are correct and no evidence that any of the effects that petitioner forecasts will occur. Indeed, since this case was heard by the Federal Circuit on interlocutory appeal, there is an incomplete record and no determination below even as to whether respondent's activities were within the scope of the infringement exemption. Accordingly, the issues that petitioner seeks to address are not ripe for consideration. In any event, even if petitioner were correct in arguing that a narrower exemption would provide more incentives for the development of new technology, these arguments should be addressed to Congress, not to this Court.

7. *Scripps Found. v. Baxter-Travenol Labs, Inc.*, 7 U.S.P.Q.2d 1562 (D. Del. 1988), does not support petitioner's claim (Pet. 7) that "the only other district court to have considered the issue concluded that section 271(e)(1) is limited to drugs." The *Scripps* case neither considered the issue nor came to the indicated conclusion. The *Scripps* case had nothing to do with medical devices. The dicta relied on by petitioner came in the course of the court's preliminary listing of the few rulings made to that time on section 271(e)(1), and the court was merely repeating, and citing, the holding of the district court below.

I. The Federal Circuit Decision Accords With the Plain Language of the Statute, the Legislative History, and Congressional Policy

A. The Plain Meaning of the Statute

The Federal Circuit decision interprets the words of section 271(e)(1) according to their plain and ordinary meaning. The petitioner nevertheless asks this Court to read section 271(e)(1) as though the phrase "drug [or veterinary biological] invention" had been used instead of the much broader term "patented invention."⁸

The ordinary meaning of the unqualified phrase "patented invention" plainly includes medical devices, and an examination of the other paragraphs of section 271 demonstrates that Congress intended the phrase to be given its plain meaning, consistently, throughout. The phrase "patented invention" appears not only in section 271(e)(1), but also in section 271(a), the basic infringement prohibition. Indeed, it is universally agreed that the phrase includes medical devices; petitioner Lilly's infringement claim presumes and depends on that construction. Congress provided no new definition for the phrase when it enacted section 271(e)(1) in 1984 or when it amended the statute in 1988. It must therefore

8. Veterinary biologicals were added to section 271(e)(1) in 1988 by partially amending the statute's original language, which had expressly excluded them. They were also given eligibility for patent extension under section 156. Pub. L. No. 100-670, 102 Stat. 3971 (1988) (hereinafter "the 1988 amendments"). This change was made to the statute during the pendency of the appeal in the Federal Circuit, after briefs were submitted but before the panel decision. The panel noted, however, that the amendments did not change its analysis (Pet.App. 4a). Petitioner relies on the 1988 amendments as clarifying the 1984 intent of Congress with respect to interpretation of "patented invention" (Pet. 9). The amendments, however, provide no such guidance. The significance of Congress' treatment of veterinary biologicals, not only in 1984 but also in 1988, is in its confirmation of the *quid pro quo* aspect of the exemption and statutory extension sections. See p.13 n.12, *infra*.

be assumed that "patented invention," when used in section 271(e)(1), has the same meaning as in pre-existing section 271(a). In the absence of a clear legislative intent to the contrary, the same words used in different parts of the same statute are intended to have the same meaning. *Atlantic Cleaners & Dyers v. United States*, 286 U.S. 427, 433 (1932).

Section 271(e)(1) provides an infringement exemption for a "patented invention" that is made, used, or sold "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." As the Federal Circuit correctly recognized (Pet.App. 5a-6a), the phrase "under a Federal law which regulates" in section 271(e)(1), both as originally enacted and as amended, describes the law under which regulation occurs, not the *patented invention* that is regulated. Medical devices are in fact regulated by the principal federal law that regulates drugs, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-392 (1982 and Supp. III 1985) ("the FFDC Act").⁹

The statutory language does not support petitioner's argument (Pet. 9-10) that the word "drugs" was specifically used by Congress as a clear and limiting definition of the exempted products. If it had intended to give the exemption the limited scope that petitioner favors, Congress would not have used the term "patented invention." In originally enacting, and in amending, section 271(e)(1), Congress twice chose to use the broad term

9. It is not legally significant, as petitioner contends (Pet. 9), that the particular guidelines relating to approvals for drugs and devices are defined in separate sections of the FFDC Act (generally section 335 for drugs and section 360 for devices). Drugs and devices are *regulated* by the *same section* of the FFDC Act — 21 U.S.C. § 331, which prohibits their introduction into commerce without those approvals. 21 U.S.C. §§ 331(d) and (p).

as the description of exempted inventions.¹⁰

B. The Legislative History Confirms the Plain Meaning of the Statutory Language

The legislative history of section 271(e)(1) is consistent with the plain meaning of the statute. Petitioner correctly observes (Pet. 12) that the legislative history indicates that Congress was particularly concerned with the need to allow FDA-required testing of generic drugs without liability for patent infringement. But regardless of the particular facts that first brought the problem to its attention, Congress legislated in broader terms, dealing with the general problem presented by the interplay between the patent laws and the FFDC Act requirement of lengthy testing before certain regulated products may be sold commercially. On the one hand, Congress recognized that the lengthy period of required noncommercial testing effectively limited the time that the patentee would have exclusive rights to market his invention commercially. H.R. REP. NO. 857, 98th Cong., 2d Sess., Pt. I, 15 (1984). On the other hand, Congress recognized that the requirement of lengthy testing had a second offsetting effect of delaying the entry of competitors into the market beyond the term of the patent if that

10. Petitioner has relied (Pet. 12 n.10) on an amicus brief filed in the Federal Circuit on its behalf by Senator Hatch and Representative Moorhead. It is well settled that the private views of a few legislators, especially those expressed years later in a nonlegislative forum, are entitled to no probative weight in determining the intent of an earlier Congress. *Blanchette v. Connecticut Gen. Ins. Corp.*, 419 U.S. 102, 132 (1974). This rule applies even though the legislators were sponsors of the bill. *Bread PAC v. Federal Election Comm.*, 455 U.S. 577, 582 (1982). In any event, it should be noted that other members of Congress believe that the Federal Circuit's construction of section 271(e)(1) was correct. See 135 CONG. REC. S3390 (daily ed. April 5, 1989) (remarks of Sen. DeConcini).

testing were preventable by the patentee until patent expiration. H.R. REP. NO. 857, Pt. I, at 46.

The Federal Circuit's decision in *Roche Prods. Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984), which held that competitors have no right to begin the required FDA testing until a patent has expired (thus providing an effective *de facto* extension of the patent during the post-expiration period of the competitor's required testing), prompted Congress to enact remedial legislation addressing these issues and overruling *Roche*. Congress adopted a balanced two-part remedy that included section 271(e)(1). Under a single title of the 1984 Act, Congress (1) enacted 35 U.S.C. § 271(e)(1) to permit FDA-regulated experimental testing by competitors prior to patent expiration in order to eliminate *de facto* extensions, and (2) enacted 35 U.S.C. § 156 authorizing the formal extension of patents to restore the time that a patentee itself had lost to experimental testing on the same product. The House Committee report explained:

It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged.

• • •

Other sections of Title II [of the 1984 Act] permit the extension of the term of a patent for a definite time

provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. REP. NO. 857, Pt. I, at 46.

As the Federal Circuit correctly observed (Pet.App. 5a-6a), this legislation was intended to overrule the court's own decision in *Roche*. The Federal Circuit noted that its own holding in *Roche* was not limited to drugs, and that the statute overruling *Roche* could not have been limited to drugs either (Pet.App. 6a, 7a).¹¹

Petitioner's argument ignores the fact that Congress intended section 271(e)(1) to be the *quid pro quo* for statutory extension under section 156, that it intended the scope of these changes to be co-extensive, and to include all products — including medical devices — that are subject to FDA-mandated testing under the FFDC Act. Petitioner itself sought and received a formal extension of the patent in suit pursuant to section 156 in order to compensate for the time that it had lost during FDA-mandated testing, yet petitioner asks this Court to limit section 271(e)(1) exclusively to drugs.

11. The possibility of a lengthy *de facto* extension is at least as great for medical devices of the kind here at issue as it is for generic drugs. Since no expedited approval procedure akin to that for generic drugs exists for medical devices (Veale, Trial Test., Day 13, pp.46-47), their approvals frequently take even longer than those for the drugs. Moreover, the absence of such "piggy-backing" procedures for devices means that there is no incentive merely to copy the older device of the patentee. Accordingly, manufacturers are likely to leap-frog the older device with a more advanced one. (The Medtronic device here, for example, contains beneficial features not found in the Lilly device. Klein, Trial Test., Day 9, pp.42-47, 51-53). To interpret section 271(e)(1) as limited to drugs would require that testing of new medical devices, as opposed to mere copies of existing drugs, would be delayed until after patent expiration. Certainly, the patent laws were intended to provide at least as much incentive to developers of new products as to those who merely copy existing ones.

Petitioner's strained interpretation of section 271(e)(1) would give itself and other patentees of FDA-regulated medical devices the best of both worlds — not only a formal patent extension under section 156, but also a lengthy *de facto* extension resulting from the inability of competitors to begin FDA-mandated testing until the expiration of the patent. This is exactly what Congress intended to prevent by enacting section 156 to provide the only form of extension for patents on such FDA-regulated products: "There should be no other direct or indirect method of extending patent term." H.R. REP. NO. 857, Pt. I, at 46. The Federal Circuit recognized this *quid pro quo* aspect of the legislation (Pet.App. 7a). Petitioner's argument ignores it.¹²

12. The 1988 amendments confirm the parallel nature and the *quid pro quo* aspect of the patent extension provision of section 156 and the infringement exemption of section 271(e)(1). The original parenthetical exclusion of "new animal drugs and veterinary biological products" in section 271(e)(1) was inserted into the then-pending bill in 1984, contemporaneously with a Judiciary Committee change to section 156 in order to delete those identical products from eligibility for statutory extension. The reason for the insertion had nothing to do with whether the products were or were not human drugs, but rather that those products were to be made the subject of a separate bill. See H.R. REP. NO. 857, Pt. I, at 7. It is no coincidence that when the 1988 amendments returned certain of those products to eligibility for section 156 patent extension, the amendments eliminated *de facto* patent extensions for the same products by replacing them within the exemption created by section 271(e)(1).

II. The Record Does Not Demonstrate Any Adverse Consequences As A Result of the Federal Circuit's Interlocutory Decision

A. There is No Basis to Presume That The Interlocutory Decision Will Have Widespread Effect

The importance of this case to the particular parties involved is not in dispute. The decision below has cost petitioner the benefit of its injunction and will negate the disproportionately large damage award that it received. But importance to the parties is not importance to the public in general.¹³

In an effort, nevertheless, to cloak this case with an aura of general significance, petitioner presents (Pet. 16-19) an imaginary parade of horrors led by the decision below. The reality is far more mundane; petitioner's alleged effects have not been demonstrated in the existing record.

Although petitioner contends (Pet. 14-20) that the Federal Circuit's decision will substantially erode patent protection for medical devices, and thereby ultimately chill their further development and production, its arguments rely on a series of unverified assumptions that are either highly questionable or demonstrably incorrect. Many of these arguments are being advanced in this Court for the first time, and accordingly they were not considered by the Federal Circuit, the court with the primary responsibility for the interpretation and administration of the patent laws. None of these arguments justifies review of this case at the present time.

13. Medtronic has challenged the grossly excessive award, and its challenge is still pending before the trial court. Contrary to petitioner's argument (Pet. 19-20), however, it was the undermining of this particular damage award by the Federal Circuit decision — not general importance of the decision itself to alleged "copiers and infringers" — that caused Medtronic's stock to rise on the decision date.

Petitioner contends (Pet. 19) that the exemption will be judicially interpreted to permit unrestrained infringement by competitors under the guise of clinical trials, and that such competitors could take a substantial share of a patent holder's market during the term of the patent. The record, however, contains no suggestion of how the exemption for medical devices will be construed. To date, no court has passed upon the scope of the exemption as it applies to medical devices. It is precisely this issue that remains to be litigated on remand to the district court, where petitioner is contesting respondent's claim that its experimental use of the devices in question fell within the statutory exemption. There is simply no basis to assume that the lower federal courts will construe the exemption so broadly as to allow wide scale commercialization of competing devices under the guise of IDE testing.

B. Petitioner's Characterization of Device Clinical Trials is Unsupported and Ignores Existing Federal Regulations

Petitioner's general characterization of device clinical trials as rampant commercialization (Pet. 16-20) not only lacks record support, but also ignores the existing regulations of the FDA.

The purpose of the FDA regulations is to ensure that all IDE testing is limited, experimental, and non-commercial. For example, a device manufacturer intending to undertake a clinical investigation must submit, as part of an application for the prerequisite IDE, a detailed investigational plan that describes, among other things, the device, the proposed test procedure, all previous studies of the device, and the proposed investigating physicians and hospitals. 21 C.F.R. §§ 812.20 and 812.25. The regulations generally prohibit medical device manufacturers to profit from the

"sale" of devices during clinical testing. If the manufacturer intends to request reimbursement during the clinical period, the FDA requires a detailed explanation of why the charge "does not constitute commercialization of the device" before it will even permit the testing to begin. 21 C.F.R. § 812.20(8).

Activities that the FDA views to be commercialization, and therefore prohibits, include test marketing of a clinical device; charging investigators a price greater than necessary to recover costs of manufacturing, research, development, and handling; and unduly prolonging any investigation. 21 C.F.R. § 812.7. Generally, when the FDA does approve a clinical test plan, it specifies the medical centers at which the investigational implants may take place and, more importantly, limits the total number of implants (Veale, Trial Test., Day 13, pp.40-42).

Petitioner implicitly assumes that these FDA regulations will not be effective or properly enforced. The policy issues that petitioner seeks to raise would require this Court to undertake a full review of the FDA regulations, the devices and testing procedures that they cover, and the economic effects that they impose in order to assess the effect of the exemption of section 271(e)(1). Yet these issues were not raised in the courts below, and the record, therefore, is totally inadequate for the Court's review. Without that record, it would be inappropriate to adopt petitioner's assumption that these federal regulations will somehow fail to serve their intended purpose.¹⁴

14. Petitioner's argument regarding the situation of CAT-scan machines or other major "long-lasting devices" in markets of limited size (Pet. 16, 19) provides an example of its untested theory. Petitioner contends that, in the case of such devices, allowing clinical trials for competitors during the patent term could substantially erode the market for the patented device. This argument, however, ignores the FDA's authority to respond to these special circumstances. For example, the FDA could limit the clinical trials

C. The Only Evidence Of Record Contradicts Petitioner's Arguments

The only evidence now in the record concerns the particular experiences of the parties in this case. Despite petitioner's arguments to the contrary (Pet. 19-20), those experiences demonstrate that respondent's testing had virtually no effect on petitioner's market or patent rights. They indicate in all events that the scope of a competitor's FDA-regulated testing is small in comparison to the patentee's FDA-approved commercialization.

Medtronic's experimentation through the time of trial involved only thirty-one units having a total value of only \$415,000 (although not all units were sold and implanted; Pet.App. 24a-25a). At the time that the district court's injunction was entered, Medtronic had an approved IDE limited to 30 additional implants (Trial Ex. 1426), and its expectation then was that it would need 200 further implants over a three-year period, bringing it well beyond the expiration date of Lilly's extended patent, to obtain PMA approval (Veale, Trial Test., Day 13, pp.50-51). By comparison, during the two-year period of its patent extension (which began in October, 1988), petitioner projects sales of over 6,000 devices for revenue of over \$100 million. These relative numbers are hardly indicative of the kind of substantial market erosion or destruction of patent rights that petitioner claims requires this Court's immediate intervention.¹⁵

to a very few machines, relying on repeated use on many different patients, rather than use of many different machines, to provide a track record for evaluation. That these competing possibilities have not been sorted out below, however, only underscores the unreadiness of the issue for review at this time.

15. Petitioner's position, and the one that Judge Newman took in reliance on it (Pet. 19; Pet.App. 12a n.4) — to the effect that Medtronic expected to realize \$11 million in clinical revenues — is based on an early projection (Trial Ex. 139) that petitioner knows (and knew during trial) would never come to pass because Medtronic never received any FDA approval of the scope upon which the projection was based. Petitioner can be expected to complain

III. This Case Presents No Constitutional Issue Requiring Review

Petitioner contends (Pet. 14-16) that section 271(e)(1), as construed by the Federal Circuit, takes a patent holder's rights without just compensation. This issue is spurious and, as a first-time argument, does not warrant review here. The particular constitutional question now raised was neither presented nor considered below. Even if the issue is one that ultimately should be reviewed by this Court, there is no justification for review on the barren record of the present case on interlocutory appeal.

In all events, petitioner's constitutional argument is without merit. It is well settled that *regulation* of rights does not, by itself, constitute a taking. *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979). Moreover, whatever interference with the patent right that petitioner, or any device patentee, might experience as a result of the section 271(e)(1) exemption has been justly compensated for by the grant of statutory extension rights under 35 U.S.C. § 156. The Judiciary Committee considered this theory of "exchange of property interest" and this Court's decision approving that theory, *Penn Central Transp. Corp. v. New York City*, 438 U.S. 104 (1978), in passing on the constitutionality of the original

NOTES (Continued)

vehemently, as it has below, about the "damage" that it will sustain, after patent expiration, from experimental testing during the patent life. Even Trial Ex. 139, upon which petitioner relies, however, shows only very low activity by respondent until 1991, after petitioner's patent expires. In all events, neither projections of post-expiration activity, nor the activity itself, is or could be an infringement. Petitioner may justifiably fear the post-expiration market place, when more advanced technology than its own will become available to the public, but it is not entitled to a further *de facto* extension to forestall the "immediate competition" that Congress has said should be encouraged. H.R. REP. NO. 857, Pt. I, at 46. Such an extension would be a direct disincentive to the innovation, for public benefit, that the patent laws are intended to promote.

act. H.R. REP. NO. 857, 98th Cong., 2d Sess., Pt. II, 30 (1984). In the particular case of petitioner, surely the two years of additional exclusivity that it has received — and the \$100 million or more that it expects to collect during its extension — are compensation enough to permit limited FDA testing by others in anticipation of the expiration of its extended patent.¹⁶

IV. Issues of Patent Policy Should Be Addressed to Congress

The policy arguments that petitioner seeks to raise are inextricably tied to the operation of the patent system. Petitioner and others who filed amicus briefs below have already had a chance to address their arguments to the Federal Circuit, the specialized court established by Congress to speak nationwide on matters of patent policy. A unanimous panel of the Federal Circuit issued the ruling in question, and the court as a whole denied rehearing *in banc*, with only one dissent.¹⁷ Moreover, since this case is now on interlocutory appeal, petitioner will have another opportunity to present its arguments to the Federal Circuit on appeal from the

16. Although petitioner raises the further issue that section 271(e)(1) is unconstitutional as applied to a patent that has not been extended (Pet. 18, n.14), petitioner, as a holder of such an extension, lacks standing to raise this issue. *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 474 (1982).

17. In an attempt to suggest an intra-circuit conflict of major importance, petitioner repeatedly relies on the fact and substance of Judge Newman's dissent from the denial of *in banc* reconsideration (Pet. 6, 7, 11, and 18). That dissent, however, was a lone one. But even if there had been some conflict within the lower court, review by this Court is not the proper way to resolve it. *Davis v. United States*, 417 U.S. 333, 340 (1974). It is the appellate court's own *in banc* procedure that has that purpose; the fact that the procedure was declined for use here suggests that there was no conflict at all.

final judgment in the case. The issues that petitioner seeks to raise are squarely within the expertise and jurisdiction of the Federal Circuit.

Nevertheless, even *if* the policy questions raised by petitioner merit further consideration, petitioner should address its arguments to Congress. The history of the legislation involved in this case demonstrates that Congress is concerned with the interplay between the patent laws and the FDA's regulatory scheme. Congress has shown no reluctance to legislate in this area, and even to overrule by statute any decisions with which it has policy-based disagreement.

Indeed, the statute here at issue was adopted within one year of the Federal Circuit's *Roche* decision, which it overruled. Subsequently, in 1988, Congress amended the patent laws to provide for formal extensions of animal drug and veterinary biological patents, and to add those same products to the testing exemption of section 271(e)(1). Legislation was introduced in 1989 to overrule the district court's decision in the present case, but the Federal Circuit's decision made passage of that bill unnecessary.¹⁸

18. Recognizing the "legal unfairness with the state of the law" caused by the district court's decision here, Senator DeConcini introduced S. 622 to make it clear that medical devices were within section 271(e)(1). He explained:

The 1984 law was explicit with respect to human drug products and, with the enactment of Public Law 100-670, is now explicit with respect to animal drug products. The law is not explicit with respect to medical devices and this must be clarified.

* * *

My bill provides the necessary statutory *clarification* for medical devices and reaffirms the purpose behind the 1984 law — to balance the rights of patent holders — who were provided with the ability to secure patent extensions — with the public good of immediate increased competition once the patent expires.

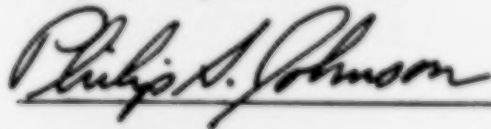
135 CONG. REC. S2861 (daily ed. March 16, 1989) (emphasis added), Pet.App. 58a-60a.

If section 271(e)(1), or the Federal Circuit's decision interpreting it, require further consideration, Congress is the appropriate forum. Indeed, the recent congressional interest in the area and the fact that legislators even now have conflicting views demonstrate that further resolution of these policy questions, if any is needed, should be undertaken by Congress, not by this Court.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted,

A handwritten signature in cursive script, reading "Philip S. Johnson", is written over a horizontal line.

Philip S. Johnson
Counsel of Record
Gary H. Levin
Albert W. Preston
Henrik D. Parker
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
One Liberty Place — 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Counsel for Respondent

Dated: September 11, 1989

OF COUNSEL:

Ronald E. Lund
Joseph F. Breimayer
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432

SEP 19 1989

JOSEPH F. SPANIOLO
CLERK

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

U.

MEDTRONIC, INC.,

Respondent.

**ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

PETITIONER'S REPLY BRIEF

TIMOTHY J. MALLOY

Counsel of Record

LAWRENCE M. JARVIS

GREGORY J. VOGLER

MCANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

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PETITIONER'S REPLY BRIEF

Through several arguments first raised in its opposition brief, respondent Medtronic, Inc. ("Medtronic") attempts to misdirect this Court away from the straightforward, purely legal issue at hand. Medtronic also mischaracterized the only portion of the legislative history quoted by it. Medtronic commenced the quotation in the middle of the paragraph and omitted the key prefatory language that clearly negates Medtronic's argument. This reply brief is necessary to address these new issues and mischaracterizations.

Medtronic sets forth a wishful but erroneous "question presented" by substituting the words "regulated by the Federal Food, Drug and Cosmetic Act (FD&C Act)" for the operative statutory language of 35 U.S.C. §271(e)(1): "under a Federal law which regulates . . . drugs or veterinary biological products." The

plain meaning of the statute contradicts Medtronic's substitution. Congress expressly referred to the FD&C Act a few lines earlier in Section 271(e)(1). Congress would not have used different language — under a Federal law which regulates . . . drugs or veterinary biological products — to describe the *entire* FD&C Act later in the same provision.

Medtronic raises new arguments on the ripeness of this appeal and an alleged lack of record to support the widespread effect and importance of the Court of Appeals' decision.¹ Both of Medtronic's arguments are directly contrary to the positions that Medtronic argued before the Court of Appeals to obtain a full review of the Section 271(e)(1) legal issue *appealed by Medtronic*. Medtronic also states for the first time, incorrectly so, that one of the patents in suit, U.S. Patent 3,942,536 ("the '536 patent"), is no longer in issue (Brief in Opp., p. 3 n. 2).

Contrary to Medtronic's suggestion, this Court, not Congress, is the appropriate forum for correcting the erroneous interpretation of Section 271(e)(1) by the Court of Appeals. Medtronic's misdirection highlights the purpose of its entire opposition brief — an attempt to distract the Court from the sole legal issue before it.²

I. The Section 271(e)(1) Legal Issue Decided By The Court Of Appeals Is Ripe For Judicial Review

The question of ripeness for judicial review turns on "the fitness of the issues for judicial decision" and "the hardship to the parties of withholding court consideration." *Abbott Labor-*

¹ Medtronic asserts that "petitioner will have another opportunity to present its arguments to the Federal Circuit on appeal from the final judgment in the case" (Brief in Op. pp. 19-20). If Medtronic is referring to Lilly's arguments relating to the single issue involved in Lilly's certiorari petition, Medtronic's argument is unfounded.

² Medtronic discusses at length the alleged, yet unproven features of its infringing devices, the features (albeit mischaracterized) of the devices of Lilly's subsidiary, the revenue that Lilly's subsidiary may receive, and the need for a full review of the FDA regulations for clinical trials. These allegations are of no controlling relevance and further demonstrate Medtronic's attempt to divert this Court's attention from the legal issue on appeal.

atories v. Gardner, 387 U.S. 136, 149 (1967). Both of these factors strongly favor ripeness of the present issue for adjudication.

The issue presented on appeal undeniably is purely legal. It will not be clarified by further factual development. *Cf. Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568, 581 (1985); *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Development Comm'n*, 461 U.S. 190, 201 (1983).

Medtronic has admitted to the Court of Appeals that the Section 271(e)(1) issue on appeal requires no further factual development:

The questions of law presented for review in this appeal do not depend on anything the lower court has yet to decide.

Supplemental Brief for Appellant Medtronic, Inc. on the standard of review, dated November 18, 1988, p. 6. For Medtronic, the ripeness of the legal issue at hand turns on whether Medtronic is the successful party on the issue at the time of the briefing. Its arguments are an attempt to misdirect this Court in order to avoid injunctive relief by delaying judicial review until the basic patent in suit, U.S. Patent Re.27,757 (the '757 patent), expires in October 1990. Unless the Court reviews the decision at this time, Lilly could lose forever its right to a complete injunction to prevent infringement of the '757 patent. The phrase "justice delayed is justice denied" applies here.

Lilly is irreparably harmed by a delay of consideration of Section 271(e)(1). The Court of Appeals' decision denies Lilly its exclusive patent position and a complete injunction against Medtronic. The district court concluded that, without an injunction, Medtronic would use "its current strength in the pacemaker industry to dominate the market involving devices for treating tachycardia and fibrillation" and that Lilly "will be irreparably harmed if Medtronic is not enjoined" (Pet. App. 37a).

The public interest would be served best by prompt resolution of Section 271(e)(1). To require the industries for medical devices, food additives, color additives and other nondrug, FDA-regulated products to proceed without certain dependable knowledge of whether Section 271(e)(1) applies to their products imposes a

considerable hardship. Without prompt judicial review, the industries involved could not be sure of the scope of their patent rights, which causes hardship on business planning.³

II. The Issue Presented Has Exceptional National Importance

Medtronic cannot credibly deny the importance of this case to the public. Medtronic already has advised the Court of Appeals that the Section 271(e)(1) issue is one "of exceptional importance to the public and to developers of medical products" (Suggestion of Medtronic, Inc. for a Hearing *In Banc*, p. 1).

The national importance of the legal issue presented is indisputable. Patent rights have been taken from patent holders in a vast range of federally-regulated industries. Over Medtronic's refusal to give consent, *amici curiae* have moved to file briefs in support of the petitioner. This activity confirms the exceptional importance of the issue raised in Lilly's petition. The Intellectual Property Owners, Inc.⁴; Bristol-Myers Co. and Zimmer, Inc.; Procter & Gamble Company; Pfizer, Inc. and Pfizer Hospital Products Group, Inc.; American Sterilizer Company; and Senator Orrin G. Hatch and Representative Carlos J. Moorhead have all filed motions for leave to file briefs *amicus curiae* expressing their views on the national importance of the issue presented and the clear error of the Court of Appeals' decision.

³ The interlocutory nature of the appeal of Section 271(e)(1) does not affect ripeness. *Cf. Northwest Airlines, Inc. v. Transport Workers Union of America*, 451 U.S. 77, 85-86 (1981) (case ripe to decide Title VII merits on interlocutory appeal); *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986) (case ripe for a determination of constitutional issue on appeal of preliminary injunction); *Smith v. Vulcan Iron Works*, 165 U.S. 518, 525 (1897) (case ripe to decide merits on interlocutory appeal in patent case).

⁴ The Board of Directors of the Intellectual Property Owners, Inc. includes two ex-Commissioners of the U.S. Patent and Trademark Office (Messrs. Donald W. Banner and William E. Schuyler, Jr.) and a "Who's Who" of patent counsel for U.S. companies. See the Appendix attached to Brief of Amicus Curiae Intellectual Property Owners, Inc. In Support of the Petitioner, p. 1a.

III. The Legislative History Contradicts Medtronic's Interpretation Of Section 271(e)(1)

In its only citation to the section's legislative history, Medtronic began the quotation in the middle of the paragraph (Brief in Op. pp. 11-12). Medtronic omitted key prefatory language from the House Committee report which immediately preceded the quotation relied upon. That prefatory language shows that the *limited experimental activity* exempted by Section 271(e)(1) is solely bioequivalency testing for generic drugs. It reads as follows:

The purpose of sections 271(e)(1) and (2) is to establish that *experimentation with a patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that *this type of experimentation* is infringement.

In *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* ___F.2d___ (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the *experimental use of a drug product* prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. [Medtronic's quotation commenced with the next word of this paragraph.]

H.R. Rep. No. 857, 98th Cong., 2d Sess. Part 1, at 45-46 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2678-79 (emphasis added). Medtronic cannot cite a single legislative statement that contemplated experimental activity other than

in the narrow context of bioequivalency testing of generic drugs.⁵

Section 271(e)(1) is not a *quid pro quo* compromise accepted for the enactment of 35 U.S.C. § 156, the patent extension provisions of the Patent Act.⁶ On the contrary, the two statutes are not coextensive. Section 271(e)(1) applies even during the original term of patents that have been extended. Section 271(e)(1) also applies to patents never extended. As is the case generally with the vast majority of medical device patents, Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.⁷

The companion provisions to Section 271(e)(1), Sections 271(e)(2) and (e)(4), provide patent protections under certain circumstances for the patent holders of "drug" and "veterinary biological products" inventions (Pet. App. 62a-63a). No similar patent protections are provided for patent holders of "medical device", "food additive" or "color additive" inventions. If

⁵ Medtronic could have avoided any alleged *de facto* extension of the patents in suit. Medtronic's expert trial witness, Mr. Paul Wylie, testified under oath that Medtronic can easily obtain FDA approval prior to patent expiration based on activities outside the United States that would not infringe the patents in suit. (Wylie Trial Test., Day 13, p. 161). See also 21 C.F.R. §814.15 (regulations permit FDA approval of medical devices based solely on foreign activities).

⁶ The legislation that eventually led to enactment of 35 U.S.C. §156 had been before Congress since 1980, well before the 1984 *Roche* decision which prompted enactment of Section 271(e)(1). See S.2892, 96th Cong. 2d Sess. (1980). Medtronic erroneously implies that Congress enacted Sections 271(e)(1) and 156 for the same reasons.

⁷ Contrary to Medtronic's arguments, the '536 patent is affected by the Court of Appeals' decision. The '536 patent expires in 1993. While Medtronic may have ceased temporarily its infringement of the '536 patent, Medtronic is permanently enjoined from infringing the '536 patent except for the exemption under Section 271(e)(1) as mandated by the Court of Appeals (District Court Order of June 28, 1989). Thus, the petitioner does have standing to raise the issue that Section 271(e)(1) is unconstitutional as applied to a patent that has not been extended (Brief in Op., p. 19 n. 16). Petitioner also raised on appeal that an expansion of Section 271 (e) (1) beyond bioequivalency testing for generic drugs raises a substantial corresponding constitutional "takings" issue. See Brief of Appellee Lilly before the Court of Appeals, pp. 26-28.

Congress had intended to include medical devices, food additives, and color additives within Section 271(e)(1), it is inconceivable that Congress would deprive the patent holders of these products the benefits of Sections 271(e)(2) and (e)(4).

CONCLUSION

The plain meaning of Section 271(e)(1) can be only that Section 271(e)(1) is limited to "drugs" or "veterinary biological products" as expressly identified therein. The statutory language "under a Federal law which regulates . . . drugs or veterinary biological products" cannot be interpreted to mean products "regulated by the entire Federal Food, Drug and Cosmetic Act" as urged by Medtronic. The decision below is clearly erroneous, and summary reversal is in order.

Respectfully submitted,

/s/ TIMOTHY J. MALLOY

TIMOTHY J. MALLOY

Counsel of Record

LAWRENCE M. JARVIS

GREGORY J. VOGLER

MCANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

Dated: September 18, 1989

No. 89-243

Supreme Court, U.S.

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**MEMORANDUM OF RESPONDENT
MEDTRONIC, INC. IN OPPOSITION TO
THE MOTION OF INTELLECTUAL
PROPERTY OWNERS, INC. FOR LEAVE TO
FILE BRIEF AMICUS CURIAE IN SUPPORT
OF THE PETITION FOR CERTIORARI**

Philip S. Johnson
Counsel of Record

Gary H. Levin

Albert W. Preston

Henrik D. Parker

WOODCOCK WASHBURN KURTZ

MACKIEWICZ & NORRIS

One Liberty Place, 46th Floor

Philadelphia, PA 19103

(215) 568-3100

Counsel for Respondent

Of Counsel:

Ronald E. Lund

Joseph F. Breimayer

Medtronic, Inc.

7000 Central Avenue, NE

Minneapolis, Minnesota 55432

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No. 89-243

IN THE
SUPREME COURT OF THE UNITED STATES

October Term 1989

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

**MEMORANDUM OF RESPONDENT
MEDTRONIC, INC. IN OPPOSITION TO
THE MOTION OF INTELLECTUAL
PROPERTY OWNERS, INC. FOR LEAVE TO
FILE BRIEF AMICUS CURIAE IN SUPPORT
OF THE PETITION FOR CERTIORARI**

Respondent, Medtronic, Inc., hereby opposes the motion of the Intellectual Property Owners, Inc. ("IPO") for leave of Court to file a brief *amicus curiae* in support of the petition for a writ of certiorari.

IPO is a lobbying group whose members are patent owners having a vested interest in enhancing the value of their patent properties (IPO Brief at 2). IPO candidly admits that its "government relations program in Washington, D.C." includes the support of "legislation to strengthen protection available under the U.S. patent . . . laws" (IPO Brief at 2). With the presentation of IPO's motion, IPO now extends its lobbying efforts to this Court.

Although the IPO implies that its brief represents the widely held beliefs of its membership, no poll was taken of its membership at large to determine whether they agreed or disagreed with the content of this brief.¹ Apparently, this brief was solicited by petitioner, Eli Lilly & Company ("Lilly").² It is understandable that IPO would grant such a request in view of petitioner Lilly's status as an active member and contributor to IPO.

The views of IPO's lobbyists are not shared by other, more prominent organizations in this field. The American Bar Association, Section on Patents Trademarks and Copyrights considered the intended scope of the experimental use exception in the wake of *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), and the enactment of 35 U.S.C. § 271(e), and adopted the following resolution:

RESOLVED, that the Section of Patent, Trademark and Copyright Law favors in principle an exemption from infringement for activities conducted solely for experimental or research purposes whether or not such activities are conducted by a commercial organization.

Resolution 101-4, passed on August 8, 1988, after full debate as to Subject 5: EXPERIMENTAL USE AFTER ROCHE V. BOLAR; printed in 1988 Summary of Proceedings, Section of Patent, Trademark and Copyright Law, American Bar Association, Chicago, Illinois, at 24.

Nor would filing of the proposed brief of the IPO materially assist the Court in deciding whether to grant *certiorari* in this case. The IPO raises issues never briefed or considered below. For example, the IPO brief focuses on agricultural chemicals regulated by the Environmental Protection Agency (IPO Brief at 5), notwithstanding the fact that the record below is virtually devoid of any mention of them. In arguing that these chemicals

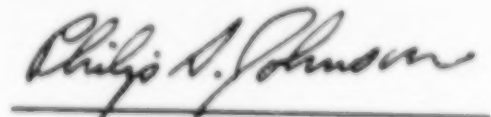
1. A copy of the proposed brief was forwarded only to members of the board of the IPO for comment.

2. Counsel for IPO, Mr. Wamsley, explained Lilly's role in prompting the filing of this brief in a telephone conference with Medtronic's counsel, Mr. Levin, during which Medtronic declined to consent to the present motion.

are affected by the Federal Circuit decision, IPO overlooks the fact that the Federal Circuit used the phrase "*any type of patented invention*" only in conjunction with the express limitation that the exempted activities be "*'solely'* for the restricted uses stated [in 35 U.S.C. 271(e)(1)]" (Pet. App. 7a). Agricultural chemicals are *not* regulated under "a Federal law which regulates . . . drugs or veterinary biological products." 35 U.S.C. 271(e)(1). Although IPO contends that agricultural chemicals may be affected by the Federal Circuit decision, neither of the parties below have contended that agricultural chemical products are entitled to receive statutory patent extensions under 35 U.S.C. 156(b), or that their EPA testing should be construed as being within the Section 271(e)(1) exemption. Presentation of these extraneous issues to the Court at this time is simply unnecessary to a decision on the merits of the pending petition.

For the reasons set forth above, the IPO motion for leave to file a brief *amicus curiae* should be denied.

Respectfully submitted,



Philip S. Johnson

Counsel of Record

Gary H. Levin

Albert W. Preston

Henrik D. Parker

WOODCOCK WASHBURN KURTZ

MACKIEWICZ & NORRIS

One Liberty Place-46th Floor

Philadelphia, PA 19103

(215) 568-3100

Counsel for Respondent

Dated: October 1, 1989

Of Counsel:

Ronald E. Lund

Joseph F. Breimayer

Medtronic, Inc.

7000 Central Avenue, N.E.

Minneapolis, Minnesota 55432

No. 89-243

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IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1989

ELI LILLY, AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
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**MEMORANDUM OF RESPONDENT MEDTRONIC, INC.
IN OPPOSITION TO THE MOTION OF
PFIZER HOSPITAL PRODUCTS GROUP, INC.
AND PFIZER INC.
FOR LEAVE TO FILE BRIEF AMICI CURIAE
IN SUPPORT OF THE PETITION FOR CERTIORARI**

Philip S. Johnson
Counsel of Record
Gary H. Levin
Albert W. Preston
Henrik D. Parker
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215/568-3100
Counsel for Respondent

Of Counsel:
Ronald E. Lund
Joseph F. Breimayer
MEDTRONIC, INC.
7000 Central Avenue, NE
Minneapolis, Minnesota 55432

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Respondent Medtronic, Inc. hereby opposes the motion of Pfizer Hospital Group, Inc. and Pfizer Inc. ("Pfizer") for leave to file their brief of *amici curiae* in support of the petition of Eli Lilly and Company for a writ of certiorari.

I. PFIZER'S INTERPRETATION OF ROCHE CONTRA- DICTS PETITIONER'S INTERPRETATION

Pfizer takes the surprising position that the Federal Circuit misread its own decision in *Roche Prods., Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d. 858, *cert. denied*, 469 U.S. 856 (1984). (Pfizer Br. at 4). Although Pfizer argues (Pfizer Br. at 3) that the *Roche* decision was strictly limited to drugs and had no

precedential effect as to medical devices, Pfizer overlooks the fact that even petitioner Lilly argued below that "*Roche* . . . controls for infringement of non-drug patents" (Lilly Brief on Appeal, at 18). The Federal Circuit agreed:

Under the *Roche* ruling, infringement would be found for the investigation testing of an infringing medical device even though, under 21 U.S.C. §360e (1982 & Supp. III 1985) of the Federal Food, Drug, and Cosmetic Act, such testing is required to obtain FDA approval to market such devices.

* * *

While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. §271(a) without regard to what particular goods might be involved.

(Pet. App. 3a, 6a). Pfizer therefore seeks to substitute its personal interpretation of *Roche* in place of that argued by petitioner and accepted by the court below. In view of this divergence of interpretation, acceptance of Pfizer's brief would not aid the Court in deciding whether the issue raised by petitioner should be heard on its merits.

II. BIOEQUIVALENCY TEST PROCEDURES ARE IRRELEVANT TO THE SCOPE OF 271(e)(1)

Pfizer argues (Pfizer Br. at 5-6) that the exemption in 271(e)(1) was intended solely to effectuate the expedited bioequivalency testing procedures for generic drugs, and therefore the exemption should be construed in light of its narrow purpose. Pfizer observes (Pfizer Br. at 5) that "there were no comparable provisions for abbreviated testing for 'generic' medical devices," and hence the exemption does not reach such devices.

Contrary to Pfizer's assertions, Congress plainly extended the exemption created by §271(e)(1) to products for which there is no expedited bioequivalent testing procedures. Pioneer new drugs are, by definition, not eligible for approval under the

expedited bioequivalency procedures¹ but the developers of such drugs are unquestionably entitled to the exemption of §271(e)(1) for the purpose of developing the safety and efficiency data required by the FDA under Section 505(b)(1) of the FDCA Act, 21 U.S.C. §355(b)(1). Similarly, the 1988 amendment of Section 271(e)(1) added veterinary biological products to the exemption despite the fact that there is no expedited approval procedure available under primary law that regulates them, the Virus-Serum-Toxin Act. 21 U.S.C. §§151-159.

Accordingly, the Federal Circuit has correctly concluded that "no persuasive reason is suggested why Congress would create an exception with respect to . . . drugs only, particularly as medical devices receive the benefit of the companion of the patent term restoration legislation." (Pet.App. 7a). The availability of bioequivalency testing for drugs is not such a reason.

III. PFIZER'S POLICY ARGUMENTS ARE UNSUPPORTED

The record and legislative history further rebut Pfizer's unsupported allegation that "the decision below significantly impedes the availability of new medical devices" (Pfizer Brief at 2). As the record indicates, numerous companies are in the process of developing new cardioverter/defibrillator devices for commercial introduction after the expiration of the Lilly patent.² Pfizer seeks to have 35 U.S.C. 271(e)(1) construed so that these

1. Pioneer new drugs are those which have never before been approved; they must be tested fully for safety and efficacy. Pioneer new drug applications therefore cannot "piggyback" on existing safety and efficacy data submitted in connection with any previously approved drug. Bioequivalency testing is used when a competitor, typically a generic manufacturer, wishes to gain approval for a competing product that is the same as or substantially similar to a drug already approved. In this case, the later applicant for commercial approval may rely upon the original safety and efficacy data, provided data is submitted to show that the proposed new product is a bioequivalent. In either instance, the testing of the drug is clearly within the scope of 271(e)(1), since the exemption of this statute is not limited to bioequivalency testing.

2. In addition to Medtronic, Teletronics and Ventritex indicated to the Federal Circuit that they are also developing new generations of such products.

new devices will be effectively kept out of the commercial marketplace for years *after* the expiration of the Lilly patent. Such a result would give Lilly a *de facto* extension of its patent in addition to the statutory two year extension it has already received.

Contrary to Pfizer's assertions however, it was not Congress' intention to grant medical device patentees statutory patent extensions while permitting them to retain the *de facto* extensions which were effectively established as the result of the ruling in *Roche*. The House Committee report explained:

It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the expiration date.

Article I, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged.

* * *

Other sections of Title II [of the 1984 Act] permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. REP. NO. 857, Pt. I, at 46. Congress' intention was to establish a fair use exception that would permit limited FDA testing so that such *de facto* patent extensions would not be available:

In this case the Committee has merely done what Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest. Just as we have recognized the doctrine of fair use in copyright, it is

appropriate to create a similar mechanism in the patent law. That is all this bill does.

H.R. Rep. No. 857(II), 98th Cong. 2d Sess. 30 (1984) (footnote omitted). Congress therefore recognized that FDA regulatory testing "does not have any adverse impact on the patent owner's exclusivity during the life of the patent." H.R. Rep. No. 857(I), 98th Cong. 2d Sess. 46 (1984). As the Judiciary Committee explained:

The patent holder retains the right to exclude others *from the major commercial marketplace* during the life of the patent. Thus, the nature of the interference with the rights of a patent holder is not substantial.

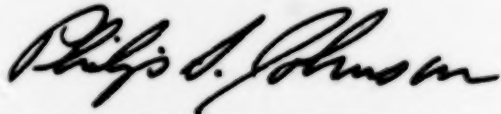
H.R. Rep. No. 857(II), 98th Cong. 2d Sess. 8 (1984) (emphasis added).

The outcome of the present case is not at odds with that envisioned by Congress. In return for the FDA regulatory delay it experienced, Lilly has extended its patent for an additional two years, during which it will sell over 6,000 units and collect over 100 million dollars. Although Medtronic may conduct FDA testing using a limited number of experimental units in the meantime, Lilly has retained the right to exclude others "from the major commercial marketplace".

IV. CONCLUSION

Pfizer has sharply criticized the Federal Circuit's view of the legislative intent, yet has failed to support its contrary interpretation with a single citation to the legislative history. Pfizer's position rests upon an interpretation of *Roche* which is contrary to that taken by both petitioner and the court of appeals. Acceptance of Pfizer's brief would be more likely to confuse the issues raised by Lilly's petition than to assist the Court in deciding whether certiorari should be granted. Accordingly, Pfizer's motion for leave to file its brief should be denied.

Respectfully submitted,



Philip S. Johnson

Counsel of Record

Gary H. Levin

Albert W. Preston

Henrik D. Parker

WOODCOCK WASHBURN KURTZ

MACKIEWICZ & NORRIS

One Liberty Place-46th Floor

Philadelphia, PA 19103

(215) 568-3100

Counsel for Respondent

Dated: *Oct 3, 1989*

OF COUNSEL:

Ronald E. Lund

Joseph F. Breimayer

Medtronic, Inc.

7000 Central Avenue, N.E.

Minneapolis, Minnesota 55432

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No. 89-243

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REPRESENTATIVE MOORHEAD FOR
LEAVE TO FILE BRIEF AMICI CURIAE IN
SUPPORT OF THE PETITION FOR
CERTIORARI**

Philip S. Johnson
Counsel of Record
Gary H. Levin
Albert W. Preston
Henrik D. Parker
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
One Liberty Place, 46th Floor
Philadelphia, PA 19103
(215) 568-3100
Counsel for Respondent

Of Counsel:
Ronald E. Lund
Joseph F. Breimayer
Medtronic, Inc.
7000 Central Avenue, NE
Minneapolis, Minnesota 55432

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CERTIORARI**

Respondent, Medtronic, Inc., hereby opposes the motion of Senator Orin Hatch and Representative Carlos Moorhead for leave to file their brief of *amici curiae* in support of the petition of Eli Lilly and Company for a writ of certiorari. The proposed brief contains little but the private *post hoc* views of the individual legislators and is therefore an unreliable vehicle for determination of the intent of the full Congress at the time of enactment of 35 U.S.C. § 271(e)(1). This Court has consistently discounted briefs and affidavits from legislators offered in support of private litigants. Continuation of this policy is proper to dissuade other litigants from attempting to enlist individual legislators to support their causes in the courts.

Although purporting to describe the views of the entirety of the 1984 Congress, the proposed *amici* brief is an improper attempt to add new evidence to the record that closed with the enactment of section 271(e)(1). It is, in essence, the private affidavit of two legislators attempting to give testimony on the beliefs and positions of hundreds of others. This Court has already held that even the *post hoc* statements of an entire congressional committee are entitled to little weight. *Weinberger v. Rossi*, 456 U.S. 25, 35 (1982). The views of individual committee members are entitled to even less; they can shed no light upon the intent of the full Congress that enacted the legislation much earlier. *Southeastern Community College v. Davis*, 442 U.S. 397, 411 n.11 (1979).

Moreover, it is immaterial whether Senator Hatch was one of the authors of the statute in question or whether he and Representative Moorhead were among its proponents. In *Bread PAC v. Federal Election Comm.*, 455 U.S. 577 (1982), this Court refused to give any weight to an affidavit submitted by the senator who had introduced the legislation, despite ambiguity in the statutory language and the legislative history:

[T]he appellants have submitted to this Court affidavits from Senator Buckley and David A. Keene, the Executive Assistant to the Senator who prepared the original draft of § 437h, expressing the belief that the amendment was not intended to exclude organizations from challenging the constitutionality of the Act. . . .

We cannot give probative weight to these affidavits, however, because "[S]uch statements 'represent only the personal views of th[is] legislato[r], since the statements were [made] after passage of the Act.' "

Bread PAC, 455 U.S. at 582, n.3 (citations omitted). Similarly, in *Blanchette v. Connecticut Gen. Ins. Corp.*, 419 U.S. 102 (1974), where an *amicus* brief was filed on behalf of thirty-six Congressmen, this Court stated:

But post-passage remarks of legislators, however explicit, cannot serve to change the legislative intent of Congress

expressed before the Act's passage. See, e.g., *United States v. Mine Workers of America*, 330 U.S. 258, 282 (1947). Such statements "represent only the personal views of these legislators, since the statements were [made] after passage of the Act." *National Woodwork Manufacturers Ass'n v. NLRB*, 386 U.S. 612, 639 n. 34 (1967).

Blanchette, 419 U.S. at 132.

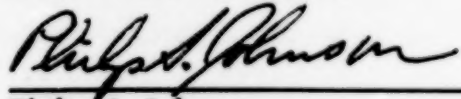
Furthermore, there is already evidence in the public record that demonstrates that the views of Senator Hatch and Representative Moorhead do not reflect the views or intent of other members of the 1984 Congress. Senator DeConcini has declared in the Senate that the Federal Circuit was correct and that its decision below did interpret section 271(e)(1) as Congress had originally intended. 135 CONG. REC. S3390 (daily ed. April 5, 1989). Senator DeConcini is the Chairman of the Patent, Copyright and Trademark subcommittee of the Senate Judiciary Committee, of which Senator Hatch is a member. Senator DeConcini's comments cast great doubt on the professed ability of the *amici* here to speak on behalf of other members of the 1984 Congress and on their purported knowledge as to what that Congress intended. In all events, the merits of conflicting senatorial views should be decided in the halls of Congress, not at the bar of this Court.

The appropriate disposition here is to deny the motion for leave to file. Private litigants before this Court should not feel the need to enlist the aid of individual legislators to champion their view of the legislative intent of Congress. The Court's acceptance of *amicus* briefs such as this one, however, would suggest that the Court in fact gives consideration to these privately solicited views. Where, as here, the submitted brief is limited to an expression of personal opinion, which has no bearing on the real issue of the earlier intent of the full legislature, it would be consistent with the Court's policy of according such a view no weight to reject this brief entirely.

In conclusion, it is respectfully requested that the motion of Senator Hatch and Representative Moorhead for leave to file

their *amici* brief in support of the petition for certiorari be denied and their proffered views be disregarded.

Respectfully submitted,



Philip S. Johnson

Counsel of Record

Gary H. Levin

Albert W. Preston

Henrik D. Parker

WOODCOCK WASHBURN KURTZ

MACKIEWICZ & NORRIS

One Liberty Place, 46th Floor

Philadelphia, PA 19103

(215) 568-3100

Counsel for Respondent

Dated: October 1, 1989

Of Counsel:

Ronald E. Lund

Joseph F. Breimayer

Medtronic, Inc.

7000 Central Avenue, NE

Minneapolis, Minnesota 55432

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ELI LILLY AND COMPANY,

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v.

MEDTRONIC, INC.,

Respondent.

**MOTION and BRIEF FOR AMICUS CURIAE THE
PROCTER & GAMBLE COMPANY IN SUPPORT OF
THE PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

RICHARD C. WITTE

Counsel of Record

RONALD L. HEMINGWAY

THE PROCTER & GAMBLE COMPANY

Ivorydale Technical Center

Cincinnati, Ohio 45217

513/627-5666

Counsel for Amicus Curiae

**In The
Supreme Court of the United States
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**MOTION FOR AMICUS CURIAE THE
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TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

Pursuant to Rule 36.1 of this Court, The Procter & Gamble Company ("P&G") respectfully moves this Court for leave to file the attached brief *amicus curiae* in support of the petition for certiorari. Movant has been unable to secure the consent of respondent.

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products which are subject to regulation by the Food and Drug Administration ("FDA"). Although the specific type of product at issue in this case is

medical devices, P&G believes the decision below directly affects a much broader range of products. Indeed, P&G submits that the decision below substantially erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives.

P&G believes that its views will be helpful to the Court in understanding the broad national effect of the decision below, especially in the areas of food additives and color additives not directly at issue in the case. P&G also believes that its views will be helpful to the Court in emphasizing the importance of the petition.

Respectfully submitted,

Dated: August 31, 1989

RICHARD C. WITTE
Counsel of Record
 RONALD L. HEMINGWAY
 THE PROCTER & GAMBLE COMPANY
 Ivorydale Technical Center
 Cincinnati, Ohio 45217
 513/627-5666

Counsel for Amicus Curiae

QUESTION PRESENTED

The Procter & Gamble Company adopts the following question presented by petitioner Eli Lilly and Company.

35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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The Procter & Gamble Company ("P&G") files this *amicus curiae* brief in support of the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.

INTEREST OF THE AMICUS CURIAE

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products which are subject

to regulation by the Food and Drug Administration ("FDA").¹ P&G also is engaged in significant research and development in these areas. P&G relies substantially upon the patent system for protecting its hard-earned inventions that result from its investments and research efforts.

Although the type of product at issue in this case is medical devices, the Court of Appeals' holding directly affects a much broader range of products. The Court of Appeals stated:

Accordingly, we hold that Section 271(e)(1) allows a party to make, use, or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

(Pet. App. 7a)² (emphasis in original).

Thus, the Court of Appeals' decision substantially erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives. The Court of Appeals' decision came as a surprise to P&G. To P&G's knowledge, no one, either in commentary or during the legislative process, had ever read the statutory language of 35 U.S.C. § 271(e)(1) the way the Court of Appeals reads it, *i.e.*, to apply to all products (in addition to drugs and veterinary biological products) regulated by the FDA or under other federal

¹ P & G is *not* a competitor of petitioner or respondent, or their subsidiaries, in the field involving the medical devices of this lawsuit.

² "Pet App. 7a" refers to page 7a of petitioner's appendix. P&G will refer to petitioner's appendix on several occasions using the same citation form.

laws.³ In addition, Senator Orrin G. Hatch (principal author of the Senate Bill that enacted 35 U.S.C. §271(e)(1) into law) and Representative Carlos J. Moorhead (primary floor manager of that legislation in the House of Representatives) expressed their view in an *amicus* brief supporting a rehearing before the Court of Appeals that the legislative history demonstrates that Congress intended Section 271(e)(1) to apply only to drugs.

P&G has a strong interest in having this Court correct the erroneous Court of Appeals' decision and restore the full scope of patent protection for food and color additive products. Because all appeals concerning patent matters and Section 271(e)(1) are within the exclusive appellate jurisdiction of the Federal Circuit pursuant to 28 U.S.C. § 1295, P&G has no other forum to determine judicially that the infringement exemption of Section 271(e)(1) excludes nondrug food additives and color additives (used in foods and cosmetics), unless this Court grants certiorari.

ARGUMENT

This case raises a federal statutory issue of exceptional national importance. It involves a purely legal issue not within the particular competence of the Federal Circuit. The Court of Appeals clearly erred in its interpretation of Section 271(e)(1). These factors make this case precisely the type in which certiorari should be granted.

A. An Exceptionally Important Statutory Issue Is Before This Court

The Court of Appeals determined that infringing medical devices and other nondrug, FDA-regulated products are entitled

³ Compare Goldstein, *The Drug Price Competition and Patent Term Restoration Act of 1984 Title II — Patent Extension Provisions*, 40 Food Drug Cosm. L.J. 363, 367 (1985) ("[W]hile the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."); Flannery & Hutt, *Balancing Competition and Patent Restoration in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307 (1985) (Section 271(e) (1) "does not include medical devices . . . food additives, color additives, or other related activities.")

to a limited noninfringement defense under Section 271(e)(1). P&G agrees with Judge Newman's conclusion in her dissent from the denial of Lilly's suggestion for rehearing in banc:

The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest.

(Pet. App. 12a).

P&G further adds that the Court of Appeals' decision affects industries other than those for medical devices. These include the industries for FDA-regulated food additives, color additives, and other nondrug products. P&G joins in the persuasive reasons set forth by Lilly in its petition for certiorari demonstrating the exceptional importance of the federal statutory issue before this Court. The Court of Appeals' decision will have a substantial economic impact on the business of P&G and a negative impact on investment for pioneering developments in the areas of food and color additives.

For example, P&G conducts safety tests, typically costing millions of dollars, to obtain FDA approval for its patented food additive products. These safety tests may take from five to fifteen years to complete.⁴ It takes another two or three years to obtain FDA approval for a food additive or color additive after filing a food or color additive petition. Thus, the complete FDA approval process, including safety testing, may take from seven to eighteen years and many millions of dollars to complete.

After P&G has paved the way for competitors by obtaining FDA approval for these pioneering inventions, competitors, in spite of any P&G patents, can use immediately the patented inventions in research to obtain FDA approval for new uses or manufacturing processes for these inventions under the Court of Appeals' interpretation of Section 271(e)(1). This can lead to a competitive advantage for P&G's competitors even though they

⁴ P&G has filed for FDA approval for a food additive called olestra, which is a fat substitute product. The safety testing for olestra has taken nearly fifteen years.

did not undertake the substantial risk and expenses in inventing and then obtaining original FDA approval for the pioneering inventions. Thus, P&G now has lost the exclusive rights to its patented inventions in important research areas. The economic impact is substantial since P&G is deprived of the exclusive opportunity to develop new uses and manufacturing processes for these patented inventions. The net effect is to lessen the incentive for P&G and other innovative companies to invent and invest in pioneering products.

B. The Court of Appeals' Decision Is Clearly Erroneous

In reaching its decision, the Court of Appeals concluded that 35 U.S.C. § 271(e)(1) was ambiguous.⁵ The Court of Appeals, therefore, resorted to the legislative history and concluded that it was the intent of Congress to overrule "in all of its ramifications" the prior decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984) (Pet. App. 7a). Notwithstanding the fact that the subject matter and holding of *Bolar* only involved drugs, the Court of Appeals concluded that it was the intent of Congress to immunize from patent infringement otherwise infringing activities conducted for regulatory purposes under any federal law regulating drugs or veterinary biological products, even if the product involved is not a drug or veterinary biological product. With respect to the Food, Drug and Cosmetic Act, for example, this means that such activities conducted with respect to seeking approval for the marketing of medical devices, food additives, and color additives are immunized, simply because the Act regulating them also regulates drugs.

The legislative history does not support the Court of Appeals' strange interpretation. The Court of Appeals did not cite any language from the legislative history, because there is none, stating in words or substance that FDA-regulated medical devices, food additives, color additives, and other nondrug

⁵ P&G disagrees and submits that the plain language of Section 271(e)(1) clearly limits its infringement exemption to drugs and veterinary biological products.

products fall within the exemption of Section 271(e)(1). Lilly's petition for certiorari sets forth the substantial legislative references establishing that Section 271(e)(1) is directed solely to drugs. See Lilly's Petition for Certiorari, pp. 12-14.

Simply put, the Court of Appeals' decision constitutes impermissible judicial legislation. See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy.").

CONCLUSION

The decision of the Court of Appeals, if left standing, will have enormous negative economic impact on America's innovative companies. Based upon the important national issue involved and the Court of Appeals' clear error, a grant of certiorari is fully justified, and even compelled, in this case.

Respectfully submitted,

/s/RICHARD C. WITTE

RICHARD C. WITTE

Counsel of Record

RONALD L. HEMINGWAY

THE PROCTER & GAMBLE COMPANY

Ivorydale Technical Center

Cincinnati, Ohio 45217

513/627-5666

Counsel for Amicus Curiae

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No. 89-243

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,
Petitioner.

v.

MEDTRONIC, INC.,
Respondent.

**MOTION AND BRIEF FOR AMICUS CURIAE
AMERICAN STERILIZER COMPANY IN SUP-
PORT OF THE PETITION FOR A WRIT OF
CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FEDERAL
CIRCUIT**

ROBERT D. YEAGER
Counsel of Record
EDWARD L. PENCOSKE
KIRKPATRICK & LOCKHART
1500 Oliver Building
Pittsburgh, PA 15222
(412) 355-6500

Counsel for Amicus Curiae

**In The
Supreme Court of the United States**

October Term, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

**MOTION FOR AMICUS CURIAE AMERICAN
STERILIZER COMPANY IN SUPPORT OF
THE PETITION FOR A WRIT OF CERTIO-
RARI TO THE UNITED STATES COURT OF
APPEALS FOR THE FEDERAL CIRCUIT**

Pursuant to Rule 36.1 of this Court, American Sterilizer Company (AMSCO) respectfully moves this Court for leave to file the attached brief *amicus curiae* in support of the petition for certiorari. Consent of Respondent was denied although Respondent indicated that, if supplied with a copy of the brief, it would further consider Movant's request. A copy of the brief, when completed, was telecopied to Respondent on 6 September. Consent was not received by the end of business that day, which was the deadline established by the printer for printing the instant motion.

AMSCO is a manufacturer of various types of capital equipment, such as sterilizers, used in the health care

industry and which are regulated by the Food and Drug Administration. It is AMSCO's position that the decision below has:

- (i) improperly expanded the narrow exception to patent infringement set forth in 35 U.S.C. §271(e)(1);
- (ii) seriously interfered with the patent rights of capital equipment manufacturers such as AMSCO; and
- (iii) raised serious Fifth Amendment questions.

AMSCO's views will be helpful to the Court in understanding the tremendous impact of the Federal Circuit's decision upon capital equipment manufacturers which, heretofore, were not believed to be encompassed within 35 U.S.C. §271(e)(1).

Respectfully submitted,

ROBERT D. YEAGER

Counsel of Record

EDWARD L. PENCOSKE

KIRKPATRICK & LOCKHART

1500 Oliver Building

Pittsburgh, PA 15222

(412) 355-6500

Counsel for Amicus Curiae

Dated: 9 September 1989

QUESTION PRESENTED

American Sterilizer Company adopts the following question presented by Petitioner Eli Lilly and Company.

35 U.S.C. §271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. §271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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**In The
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MEDTRONIC, INC.,
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**BRIEF FOR AMICUS CURIAE AMERICAN
STERILIZER COMPANY IN SUPPORT OF
THE PETITION FOR A WRIT OF CERTIO-
RARI TO THE UNITED STATES COURT OF
APPEALS FOR THE FEDERAL CIRCUIT**

American Sterilizer Company (AMSCO) files this *amicus curiae* brief in support of the petition of Eli Lilly and Company (Lilly) for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.

INTEREST OF THE AMICUS CURIAE

AMSCO is a capital equipment manufacturer. Some of its equipment is regulated by the Food & Drug Administration (FDA). The decision of the court below has dramatically expanded the narrow exception to patent infringement enacted by Congress in 35 U.S.C. §271(e)(1). Such a broad interpretation of that statute has seriously eroded AMSCO's patent rights and the rights of all such capital equipment manufacturers. The erosion of AMSCO's patent rights is evidenced by the actions of the defendant in a civil action now pending in the Northern District of Texas, Fort Worth Division, in which AMSCO sued for patent infringement. (Civil Action No. CA-4-89-238-K). The defendant has raised 35 U.S.C. §271(e)(1), as interpreted by the Federal Circuit, as a defense. Thus, AMSCO has a compelling interest in having this Court correct the erroneous decision below and restoring to it the full measure of protection afforded by its patents.

ARGUMENT

A. The Decision Of The Court Of Appeals Is Clearly Erroneous

The Federal Circuit had before it a legal issue involving statutory interpretation. Surprisingly, the decision is not based on the language of the statute because "each [party] has put forth equally plausible interpretations of section §271(e)(1), which to us means the language is fraught with ambiguity." *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402, 405 (Fed. Cir. 1989). Faced with that "ambiguous" language, the court failed to look to the legislative history for guidance because "each side has been

able to highlight general statements in the legislative history which allegedly support their own reading of §271(e)(1)." 872 F.2d at 405.

Rather than rely on standard canons of statutory construction, such as analyzing the language of the statute and the legislative history, the court took a different tack. The court started off well enough with the proposition that "§271(e)(1) was added to overrule this court's decision in *Roche* [*Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)]." 872 F.2d at 406. However, the court erred when it failed to review the legislative history to ascertain what Congress thought the *Roche* decision meant. Instead, the court substituted *its* interpretation of the *Roche* decision. By relying on its version of the meaning of *Roche* instead of reviewing the legislative history to ascertain Congress' understanding of *Roche*, the court engaged in improper legislation in the guise of statutory interpretation.

To support the conclusion that it reached, the court stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." 872 F.2d at 406. That statement belies a fundamental misunderstanding of the ways that drugs and medical devices are approved. Generic drug approval is obtained by performing a series of tests to establish bioequivalency. Because medical devices encompass a wide variety of devices from implantable cardiac pacemakers, to sterilizers, to snake bite kits, there is no one, well defined, series of tests which must be satisfied. The tests may involve, for example, placing a large piece of capital equipment at several potential customers' sites and allowing that

piece of equipment to be operated over a period of several months. During that period, salesmen as well as technical people continually call upon the potential customers. That situation is substantially different from bioequivalency testing which may be carried out in the generic drug manufacturer's own laboratories. Such differences could well be the basis for Congress' creation of an exception for drugs but not medical devices.

B. The Court's Decision Has Serious And Far Reaching Constitutional Implications

In enacting §271(e)(1), Congress was very concerned with the constitutional ramifications of creating an exception to patent infringement. Congress carefully reviewed those constitutional ramifications in the context of *bioequivalency* testing. In that narrow context, Congress concluded that the nature of the interference was not substantial. H. R. Rep. No. 857, 98th Cong., 2d Sess. Part 2, *reprinted in* 1984 U.S. Code Cong. & AD. News 2647, 2692. No such constitutional analysis has been performed with respect to medical devices although the Federal Circuit's interpretation of §271(e)(1) purports to include medical devices within the exception of that section. Because of the wide range of devices apparently now falling within the scope of §271(e)(1), no court is in a position to envision all of the ramifications of such a sweeping change in the law. By making a whole host of heretofore infringing activities apparently no longer infringing activities, serious constitutional questions have been raised. Such a sweeping change should be left to Congress where capital equipment manufacturers will have an opportunity to state their case.

CONCLUSION

For the foregoing reasons, *amicus curiae* respectfully requests that this Court grant the Petition for Certiorari.

Respectfully submitted,

/s/ ROBERT D. YEAGER

ROBERT D. YEAGER

Counsel of Record

EDWARD L. PENCOSKE

KIRKPATRICK & LOCKHART

1500 Oliver Building

Pittsburgh, PA 15222

(412) 355-6500

Counsel for Amicus Curiae

Dated: 9 September 1989

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF
AND BRIEF FOR AMICI CURIAE
ZIMMER, INC. AND BRISTOL-MYERS CO. IN
SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Of Counsel:

TIMOTHY WENDT
PAUL DAVID SCHOENLE
ZIMMER, INC.
P.O. Box 708
Warsaw, Indiana 46580

September 11, 1989

DONALD O. BEERS
(Counsel of Record)
KATHERINE L.Q. BRITTON
DAVID E. KORN
ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 728-4901
*Counsel for Amici Curiae
Zimmer, Inc. and
Bristol-Myers Co.*

IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-243

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

MOTION OF ZIMMER, INC. AND BRISTOL-MYERS CO.
FOR LEAVE TO FILE BRIEF OF AMICI CURIAE IN
SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Zimmer, Inc. is a manufacturer of medical devices and, in particular, orthopedic implants to repair or reconstruct crippling skeletal defects. It is the holder of patents for many medical devices and expends considerable resources in developing innovative new devices. Its many patented medical devices are subject to approval by the

Food and Drug Administration ("FDA"). Bristol-Myers Co. is the parent company to Zimmer.

Petitioner Eli Lilly and Company ("Lilly") is seeking a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit interpreting 35 U.S.C. § 271(e)(1) as providing that certain "experimental" uses of a patented medical device in connection with submission of data to the FDA are not patent infringements. That decision, which came as a complete surprise to members of the medical device manufacturing community familiar with the statute, may be expected to have a substantial adverse economic effect on the medical device businesses of Zimmer and Bristol-Myers and of other similarly situated medical device manufacturers. In addition, the decision will have a substantial adverse effect on innovation in such medical device businesses. Therefore, both Zimmer and Bristol-Myers have a strong interest in review of that decision. Accordingly, both companies move this Court for leave to file their brief as amici curiae in this matter.

The accompanying proposed amici curiae brief sets out the arguments that Zimmer and Bristol-Myers wish to make to the Court concerning the reasons for granting Lilly's petition for a writ of certiorari. Zimmer and Bristol-Myers respectfully submit that, as members of the medical device industry with patented products potentially affected by the decision of the Circuit Court in this matter—but as companies without a direct interest in the specific products being contested—they are in a position to offer a useful perspective to the Court on the issues presented. Zimmer and Bristol-Myers thus request that their motion be granted and that their amici curiae brief be considered by the Court in the context of the pending petition for a writ of certiorari.

Counsel for Zimmer and Bristol-Myers has contacted counsel for the parties to seek their consent to filing of

this brief. Counsel for Lilly has consented in writing.¹ Counsel for Medtronics has withheld its consent.

Respectfully submitted,

DONALD O. BEERS
(Counsel of Record)
KATHERINE L.Q. BRITTON
DAVID E. KORN

ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 728-4901

*Counsel for Amici Curiae
Zimmer, Inc. and
Bristol-Myers Co.*

Of Counsel:

TIMOTHY WENDT
PAUL DAVID SCHOENLE
ZIMMER, INC.
P.O. Box 708
Warsaw, Indiana 46580

September 11, 1989

¹ See Letter dated August 25, 1989 from Timothy J. Malloy, counsel of record for Lilly, to Donald O. Beers consenting to filing of *amicus* brief by Zimmer and Bristol-Myers. This letter is being filed with the Clerk with this motion.

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BRIEF OF AMICI CURIAE ZIMMER, INC. AND
BRISTOL-MYERS CO. IN SUPPORT OF PETITION
FOR WRIT OF CERTIORARI

INTEREST OF AMICI CURIAE

Zimmer, Inc., a manufacturer of medical devices, and Bristol-Myers Co., its parent corporation (hereafter referred to collectively as "Zimmer") file this brief as amici curiae in support of the petition of Eli Lilly and Company ("Lilly") for a writ of certiorari to review the decision of the Court of Appeals for the Federal Circuit in this matter. In that decision, issued on March 29, 1989, the Circuit Court interpreted 35 U.S.C. § 271 (e) (1) to apply to medical devices as well as drugs, thus cur-

tailoring the patent protection applicable to medical devices. If the decision is allowed to stand it will have potentially enormous adverse economic effects on the business of Zimmer and similarly situated manufacturers of medical devices.¹ More importantly, affirming this decision will curtail innovation by all United States manufacturers of medical devices at a time when innovation is greatly needed to address the numerous health care problems of our aging population.

SUMMARY OF ARGUMENT²

The decision below interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984³ to state that it is not an act of infringement to make, use, or sell a patented medical device for uses reasonably related to the development and submission of information to the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. That provision, codified at 35 U.S.C. § 271(e)(1), was written to allow limited testing of *drugs* during patent terms—testing that would not involve sales of the infringing products to potential customers of the patent owner. Congress never intended the statute to apply to *non-drug* products, as both the statute's terms and its legislative history make clear. Because medical devices differ from drugs in their development and regulation in significant ways, the effects of Section 271(e)(1) on innovation in the medical device industry are different from, and much greater than, the statute's effects on

¹ The medical device industry is of substantial importance to the United States economy, involving an estimated more than \$24 billion in shipments for 1989, with an international trade surplus estimated at \$1.3 billion. U.S. Dept. of Commerce, *U.S. Industrial Outlook 1989* 32-1 (1989).

² Amici adopt the statement of the issues and of the case included in the Lilly petition.

³ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

drug innovation. The ramifications of the Circuit Court's decision are of such consequence, to amici and to the country generally, that the Court should grant certiorari. Because the decision is quite clearly wrong, summary reversal is appropriate.

ARGUMENT

I. THE DECISION BELOW WILL HAVE A SERIOUS ADVERSE IMPACT ON THE MEDICAL DEVICE INDUSTRY AND THE PUBLIC

The Circuit Court's interpretation of 35 U.S.C. § 271(e)(1) means that a patent owner is powerless to prevent marketing of an otherwise infringing medical device if that marketing is solely for uses reasonably related to the development and submission of information under the Federal Food, Drug, and Cosmetic Act. The immediate effect of this decision will, of course, be its significant economic consequences on the litigants, and on similarly situated litigants. The near term effects will predictably be the introduction of copy-cat medical devices during existing patent terms, undercutting the value of current patents unfairly. The longer term effects are, however, the most serious, not only for the companies affected, but also for the patients who might utilize those companies' products: This decision must, necessarily, significantly alter business planning in the medical device industry.

Innovation, in this field as in others, requires creativity, perception, hard work—all human qualities that will not disappear because of a court decision. Innovation also requires, however, money, often a great deal of money. Businesses can (and will) only devote large amounts of money to research and development if they can have some assurance that the fruits of that research will provide an adequate return to justify the cost. Here, the Circuit Court has reduced effective patent terms, during which research costs can be recovered, by as much

as five years or more. In some cases, the years denied protection are the most important in the product's life. Moreover, with respect to some types of medical devices, the decision has, as a practical matter, removed effective patent protection altogether. The ultimate effect of the Circuit Court's decision is predictable—medical device executives must now cut back on research and development expenditures.

An understanding of why the effect of the Circuit Court's decision is so significant requires an understanding of the particular characteristics of the medical device industry and of the system for regulatory approval of medical devices:

A. Characteristics of Medical Devices

The term "device" as defined by the Federal Food, Drug, and Cosmetic Act includes an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" used for medical purposes. 21 U.S.C. § 321(h). This definition encompasses a wide variety of products, ranging from tongue depressors to sophisticated medical machinery. Consequently, medical devices are divided into three classes, with Class III encompassing the more sophisticated devices. See 21 U.S.C. §§ 360c-360e. The types of devices in Class III include the automatic implantable cardioverter defibrillator at issue in this litigation, certain orthopedic products manufactured by Zimmer, CAT-scans and other diagnostic machinery, and many other lifesaving medical devices.

B. Regulatory Approval of Medical Devices

Only Class III medical devices require premarket approval. See 21 U.S.C. § 360(e).⁴ Within Class III, all

⁴ Premarket clearance for such medical devices was first required in 1976 by the enactment of the Medical Device Amendments of 1976. Pub. L. No. 94-295, 90 Stat. 540 (1976).

new devices introduced after 1976 require premarket approval by the FDA. However, pre-1976 medical devices in Class III and devices that can be shown to be "substantially equivalent" to such pre-1976 devices only require premarket approval if the FDA, by regulation, specifically requires such approval. See 21 U.S.C. §§ 360c(f), 360e(a)-(b). Premarket approval, where required, involves submission to the FDA of safety and effectiveness test data, as well as other data and information. In some cases, a device manufacturer who argues that its device is "substantially equivalent" to a pre-1976 medical device and thus not subject to premarket approval may also be required to develop safety and effectiveness data to support that position. Testing of an unapproved medical device is permitted upon FDA clearance of an Investigational Device Exemption ("IDE"). See 21 C.F.R. Part 812 (1988).

When safety and effectiveness data are required, the same information must be developed and the same regulatory requirements apply for copies of existing, patented products as for new products. There are no abbreviated procedures available for establishing the safety and effectiveness of copies of patented devices as there are for the drug products to which the statute at issue was intended to apply. See 21 U.S.C. §§ 355(b)(2), 355(j).⁵

To generate the safety and effectiveness data required for FDA approval, medical devices must generally be used in a treatment context. That may mean permanent implantation of a device during its investigational stage. For example, hip stem replacements of the type produced by Zimmer must be implanted in patients in clinical trials of the devices. Development of necessary safety and effectiveness data may, with respect to some devices, require major purchases of the devices by hospitals or clinics, again during the investigational stage. For ex-

⁵ See discussion in Section II, *infra*, regarding Congressional intent that Section 271(e)(1) should apply to drugs.

ample, diagnostic machines such as CAT-scans must be used in hospitals over an extended period of time to develop data for submission to FDA.

Zimmer's recent experience with a patented invention provides a good example of the length of time during which investigations sometimes must be conducted before FDA approval is obtained. Zimmer cooperated with two leading orthopedic surgeons to develop an innovative hip stem replacement known as the "Bias™ hip prosthesis." This patented medical device received FDA approval for use without bone cement in February 1989. The device, however, was introduced in the market for clinical testing purposes for use without bone cement in 1982, and the application for premarket approval was filed in 1984.

C. Sales of Medical Devices As Part of the Investigational Stage

The clinical testing necessary for obtaining FDA approval of Class III medical devices is also vitally important to develop a reputation for innovation and to control quality, points which are important for the subsequent success of the manufacturer's products (including devices other than the one under investigation). Moreover, clinical testing of medical devices—unlike the bioequivalence testing of drugs that Section 271(e)(1) was written to cover⁶—often involves substantial sales of the device being investigated. FDA regulations for medical devices allow medical device companies to recover their cost of manufacture, research, development, and handling of a device while it is being tested. 21 C.F.R. § 812.7(b) (1988).

A medical device manufacturer may not promote or commercialize an investigational medical device. Where individual devices are expensive and a large number of patients must be utilized to allow the company to develop

⁶ See Section II.D *infra* for a discussion of bioequivalence testing of drugs.

statistically significant data to justify FDA approval, however, the dollar amount of sales for an investigational device can mount rapidly.

. . .

It is not difficult to predict the consequence if the Circuit Court's decision is allowed to stand. Patent infringers will enter the market for a product like the Bias™ hip prosthesis as soon as their copies of the patented products can be developed. They will, perfectly legitimately, file an IDE and begin selling their copy as part of their own investigations of the safety and effectiveness of the copy. The investigational process will necessarily stretch on for years to gather data on long term stability, even assuming good faith on the part of all concerned, but no actionable patent infringement will occur until the date of approval. (If the patent term expires before the date of approval, there may never be actionable infringement.) To take an example important to Zimmer—with many orthopedic manufacturers conducting potential clinical studies of a Bias™ hip, the number of patients receiving the innovative product will be substantial and Zimmer's "leap of faith" to develop an innovative product will, in the absence of patent protection, merely benefit all other orthopedic manufacturers who follow Zimmer's lead.

The characteristics of uses of medical devices make this effect particularly damaging to the innovator medical device industry. Unlike the situation with drugs (for which non-patient volunteers are utilized for bioequivalence testing), a patient receiving a hip stem replacement from a copier during the investigational period will not be available as a customer for the innovator if the copier can only be stopped at the point of approval of its product. No one is going to remove an implanted hip stem that is performing satisfactorily. That customer is irretrievably lost to the innovator. Similar effects are predictable with respect to high cost reusable machinery.

Such machinery may be extremely expensive, in some cases running more than one million dollars per unit, and a hospital may only be able to afford one such device. Consequently, investigational sales may successfully lock up the market for that device prior to FDA approval.

Innovation in the medical device industry is very rapid. Given the length of time required for FDA approval, many devices may be becoming obsolete by the time that the devices receive approval. Thus, the principal sales of those types of devices will be during the investigational period. Intraocular lenses are a good example of medical devices which have been primarily marketed during the testing period. It is not uncommon for an intraocular lens to be considered outdated by the time that lens is approved.

In a very innovative sector of the medical device industry, therefore, the Circuit Court's decision makes patent protection almost totally illusory. By the time a patent can be enforced (*i.e.*, the date of approval for the copier), the copier will surely have moved on to investigate (and in the process market) an updated product.

The effect of this decision on business planning in the medical device industry is self-evident. If patent protection for an innovation is significantly devalued, less can be spent on research and development. If innovator companies are generally the losers from the decision—as they undeniably are—and copiers are the winners, investors will put their money in copying companies, again diminishing available resources for innovation. Ultimately, the greatest loss will be to patients who might have benefited from innovation that will not occur.⁷

⁷ In addition, because this decision disadvantages innovation in the United States, which is now a leader in the development of new medical devices, the decision will have adverse trade consequences.

II. THE DECISION BELOW WAS IN ERROR

A. The Plain Meaning of the Statute is at Odds With the Circuit Court's Decision

Section 271(e)(1) in its present form states that:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).⁸

It is clear that courts are bound by the specific statutory language in construing statutory provisions. *See, e.g., United States v. James*, 478 U.S. 597, 604-606 (1986). Zimmer respectfully suggests that the ordinary reading of the quoted statutory language is that it grants a narrow exemption from patent infringement for developing information necessary to obtain approval for drugs and veterinary biological products.⁹ Inexplicably,

⁸ The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

⁹ As Lilly's petition for certiorari sets out and as discussed in Sections II(B) and II(C), *infra*, confirmation that that reading is the common one is found in the legislative history of Section 271(e)(1) as passed in 1984 and in discussions of commentators. Further confirmation is also found in the early legislative history of the 1988 amendment to Section 271(e)(1) which brought animal

however, the Circuit Court has read the provision as granting an exemption from patent infringement not only for developing information necessary to obtain approval of drugs and veterinary biological products but also for developing information necessary to obtain approval of a wide spectrum of other products, including medical devices and some food products and ingredients.¹⁰

The Circuit Court's interpretation undeniably requires a strained reading of the plain language of the statute. To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the Federal Food, Drug, and Cosmetic Act and the Biologics Act of 1902 (the other statute under which FDA approves some (biological) drugs). This reading simply cannot be squared with the caveat in Section 271(e)(1), which explicitly refers to the "Federal Food, Drug, and Cosmetic Act."

Contrary to the Circuit Court's suggestion, this unusual reading of Section 271(e)(1) as covering products other than human and veterinary drugs cannot be justified by noting that Section 271(e)(1) uses the term "pat-

drugs within the ambit of that section. See S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986), describing the proposed amendment:

This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to human pharmaceuticals.

(Emphasis added.)

¹⁰ The Court's reading also changes patent infringement law with respect to food additives, color additives, and some food products as to which information must be submitted to FDA to justify a change in a food standard. See 21 C.F.R. §§ 71.1, 171.1 (1988) (describing data submission requirements for color additive petitions and food additive petitions respectively); 21 C.F.R. § 130.17 (1988) (temporary permits allowing marketing of food to gather information to support a petition to amend a food standard).

ented invention" rather than the term "patented drug." The use of the term "invention" is explicable by the fact that Congress was dealing not only with product patents but also with patents for drug compositions and patents for uses of drugs. Thus the term "patented drug" would have been potentially unclear, whereas the term "invention" clearly covers patents for drug products, composition, and use. Moreover, the term "patented invention" is the term used in 35 U.S.C. § 271(a) which Section 271(e)(1) modifies.¹¹

B. The Circuit Court's Interpretation is Inconsistent with Congress' Clear Intent

The Circuit Court's interpretation also violates the well-established principle of statutory construction that courts are required to defer to the intent of Congress if there is any doubt about the meaning of the words. See, e.g., *Mackey v. Lanier Collections Agency & Service, Inc.*, — U.S. —, 108 S.Ct. 2182, 2191 (1988). The Circuit Court's decision seems to be based on its own view of possibly applicable policy considerations (Pet. App. 7a). The court, however, was not free to substitute its policy choices for those of Congress and rewrite the legislation. See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979).

The legislative history of Section 271(e)(1) as enacted¹² unambiguously demonstrates that Section

¹¹ Section 271(a) states that "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

¹² It is appropriate to look at Congress' intent in 1984 in enacting Section 271(e)(1) because the original version of Section 271(e)(1) included both the disputed phrase "a Federal law which regulates the manufacture, use, or sale of drugs" and an explicit reference to the "Federal Food, Drug, and Cosmetic Act." The 1988 amendment does not change the analysis. To the contrary, it con-

271(e)(1) was intended to apply only to drugs. Thus, in a House Report, the Committee stated that "the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 8 (1984). (Bioequivalence is equivalence in the rate and extent of absorption of a drug. See 21 U.S.C. § 355(j)(7)(B).) The same Report also refers to "provisions of the bill which permit the limited testing of drugs while they are on patent in order to assist in the preparation of an abbreviated new drug application." *Id.* at 29. See also 130 Cong. Rec. H8,708 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (provision will allow generic manufacturer to "obtain a supply of a patented drug product during the life of the patent and conduct tests using that product"); *id.* at H8,712 (statement of Rep. Kindness) ("this bill would provide that the generic drug manufacturers can start playing around with the drug on which the patent is about to expire within a year").

That this provision was understood by Congress to differentiate between pharmaceuticals on the one hand and all other types of patented products on the other is made clear in the statement of Rep. Moorhead, 130 Cong. Rec. H9,143 (daily ed. Sept. 6, 1984), who criticized the provision for that reason, saying:

There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder.

If the legislative history were not already clear enough, Congress' intent is further elucidated in the

firms that Congress intended to limit Section 271(e)(1) to specifically identified products, i.e., human drugs and veterinary drugs and biologicals.

amicus brief in support of Lilly's request for rehearing en banc filed by Senator Hatch, the principal Senate author of the 1984 legislation, and Rep. Moorhead, a primary floor manager of the bill in the House. In that brief, Senator Hatch and Rep. Moorhead reiterate that Section 271(e)(1) was intended to apply only to drugs. Brief of Senator Hatch and Representative Moorhead at 2.

C. The Medical Device Industry Had No Notice That Section 271(e)(1) Might Be Interpreted To Apply to Medical Devices

The extent of the Circuit Court's departure from both the words of the statute and Congress' expressed intent is suggested by the fact that its interpretation, extending Section 271(e)(1) to medical devices and other products, was totally unexpected by those in the medical device manufacturing community familiar with the statute. There had been no indication anywhere in the legislative history that Section 271(e)(1) was intended to apply to medical devices. In fact, the legislative history of Section 271(e)(1) made no reference at all to medical devices, and the medical device industry had no input on the issues relevant to extending Section 271(e)(1) to medical devices.¹³

¹³ Some innovator firms with medical device subsidiaries were involved in the negotiations which led to the Drug Price Competition and Patent Term Restoration Act of 1984. Thus, for example, Bristol-Myers Co. is cited as an active participant in the negotiations that led to the 1984 Act, as are Johnson & Johnson and American Home Products, other health care companies that have both drug and device subsidiaries. See, e.g., 130 Cong. Rec. S10,504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch). This may account for the inclusion of medical devices in the patent term restoration provisions of the Act. However, there is no evidence that these companies expressed any views on the advisability of applying Section 271(e)(1) to medical devices. Nor is there record in the legislative history of Section 271(e)(1) of any involvement by proponents of easier market access for generic copies of medical devices.

If Congress had intended to include medical devices within the ambit of Section 271(e)(1), it is inconceivable that medical device patent holders would have had no involvement in the process and no opportunity to provide Congress with information on the significant, adverse effects of such legislation on a vitally important high technology industry and on the public. The conclusion that there would have been input from the medical device industry if Section 271(e)(1) was intended to reach medical devices is reinforced by the fact that the legislative history of the 1984 legislation clearly shows that Section 271(e)(1) was drafted after extensive input from both generic and innovator drug manufacturers. *See, e.g.*, 130 Cong. Rec. H9,123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs").

The Circuit Court's reading of Section 271(e)(1) was all the more unexpected because it departs from the reading of the statute both by commentators and by the only other courts to have considered the matter. To our knowledge, prior to this decision, no commentator had ever read Section 271(e)(1) to apply to any product other than drugs (and since 1988 to veterinary drugs and biological products). To the contrary, several commentators agreed that the 1984 legislation "is limited to human drugs, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985); accord, A. Fox & A. Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984* 178, 187 (1987).

Similarly, the few judges to have considered the issue prior to the Circuit Court's ruling all read Section 271(e)(1) as limited to drugs. In the instant case, both the district court and the panel of the Circuit Court which denied Medtronic's motion to stay the injunction entered below pending appeal found that Section 271(e)(1) applies only to drugs. The only other district court opinion to discuss the issue states that "[i]t is also clear that section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 U.S.P.Q.2d 1562, 1565 (D.Del. 1988) (dictum).

D. The Intended Effect of Section 271(e)(1) as Applied to Drugs Differs From The Effect Of Its Application To Medical Devices

Given the significant differences between drugs and devices, and between applicable regulations, none of the problems involved in extending Section 271(e)(1) to medical devices apply if that section is limited to its clear language and read to apply only to drugs (and veterinary biological products). Unlike many medical devices that are durable and subject to either continued use by a patient (for example, implants) or multiple uses (for example, x-ray or ultrasound machines), most drugs are subject to one-time use because they are administered to the body through ingestion, injection, or absorption through the skin. Likewise, the regulation of drugs is substantially different from the regulation of medical devices, especially with respect to generic copies of approved drugs.

In Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, Congress amended the drug approval statute to allow approval of generic copies of approved drugs on the basis of "bioequivalence" tests rather than the full safety and effectiveness trials otherwise necessary to justify FDA approval of a drug prod-

duct.¹⁴ In these tests, the generic company administers its generic copy to a limited number of human subjects (who usually do not have the illness for which the drug is indicated)¹⁵ and, in the same test, administers the innovator product to human test subjects. It then determines whether the rate and extent of absorption of its drug and that of the innovator drug are equivalent. Cf. 21 U.S.C. § 355(j) (7) (definitions of bioavailability and bioequivalence). Upon submission of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of either an abbreviated new drug application submitted pursuant to 21 U.S.C. § 355(j) or a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b) (2).

The main effect of Section 271(e) (1) in the context of drugs is to allow the completion of such bioequivalence testing prior to patent expiration. Although Section 271(e) (1) would allow non-bioequivalence testing of generic drugs if that testing were designed to obtain drug approval, the ordinary route to approval of a copy of a patented drug would be through bioequivalence testing, not through full clinical trials. Drug testing that would involve infringement of a drug patent but would not involve testing of a generic drug would be rare.

Unlike clinical trials of medical devices that infringe patents, bioequivalence testing of generic drugs has a *de minimis* effect on manufacturers of patented drugs. Since

¹⁴ See 21 U.S.C. § 355(j). Title I is undeniably applicable only to drugs and not medical devices. Thus, Congress clearly intended some provisions of the 1984 legislation to apply to drugs only and some to apply to drugs and devices. Congress spoke clearly when it intended to include devices. See, e.g., 35 U.S.C. § 156(f).

¹⁵ Test subjects who are ill will generally be used in bioequivalence tests only for drugs (such as cancer drugs) which are too toxic to be administered ethically to persons who will not receive a benefit from their use.

bioequivalence testing generally does not involve treatment of patients or permanent use of the product, bioequivalence testing does not take potential customers away from manufacturers of patented drugs during the life of the patent. Moreover, bioequivalence testing does not allow generic manufacturers to profit from copying a patented drug during the life of the patent because, as a practical matter, bioequivalence testing is never the subject of requests to FDA to allow companies to seek reimbursement of their costs of treatment of test subjects. Therefore, despite Section 271(e) (1), manufacturers of patented drugs continue to enjoy exclusive sales during the life of the patent.

In fact, Congress specifically addressed the question of whether Section 271(e) (1) would result in a significant diminution of a drug patent owner's rights. Congress determined that any effect would be minimal because all that would be involved was bioequivalence testing. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 30.

Moreover, when Congress limited the scope of patent protection for human drugs in 1984 and for veterinary drugs in 1988, it provided some offsetting patent benefits to the innovator manufacturers, benefits that were not provided to innovator device manufacturers.¹⁶ In 35 U.S.C. § 271(e) (2), Congress provided that it would be an act of infringement to submit an abbreviated new drug application ("an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act") or a paper new drug application ("an application . . . described in section 505(b) (2) of such Act") with the intention of obtaining marketing approval before patent expiration. Likewise, when Congress created an infringe-

¹⁶ Patent term restoration was made available for some medical devices, but included limitations so that not all medical devices with patent terms effectively devalued by the Circuit Court's decision would be eligible for restoration. See 35 U.S.C. § 156(a).

ment exception applicable to animal drugs and veterinary biological products by adding them to Section 271(e)(1), it also provided that it would be an act of infringement to submit an abbreviated new animal drug application ("an application under section 512 of such Act") with the intention of obtaining marketing approval before patent expiration. 35 U.S.C. § 271(e)(2)(B).

Congress also required that an applicant submitting an abbreviated new drug application or new animal drug application with an intent to market the product in defiance of a patent claim notify the patent holder of the submission and of the basis for the copier's belief that the patent is invalid or not infringed. 21 U.S.C. §§ 355(j)(2)(B), 360b(n)(2)(A). Then, if the patent holder sues within 45 days of receipt of the notice, FDA approval of the abbreviated new drug application or abbreviated new animal drug application is automatically delayed for 30 months. 21 U.S.C. §§ 355(j)(4)(B)(iii), 360b(c)(2)-(D)(iii). Thus, specific protections for the human *drug* patent holder were incorporated into the 1984 statute, and similar protections were incorporated for animal drug patent holders in 1988. No such similar protections were added for the medical device patent holder.

CONCLUSION

For all the foregoing reasons, Zimmer respectfully submits that the Court should grant Lilly's petition for a writ of certiorari. Moreover, because the Circuit Court's decision so clearly departs from the plain language of the statute and clear legislative intent, that decision should be summarily reversed.

Respectfully submitted,

DONALD O. BEERS
(Counsel of Record)
KATHERINE L.Q. BRITTON
DAVID E. KORN

ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 728-4901

*Counsel for Amici Curiae
Zimmer, Inc. and
Bristol-Myers Co.*

Of Counsel:

TIMOTHY WENDT
PAUL DAVID SCHOENLE

ZIMMER, INC.
P.O. Box 708
Warsaw, Indiana 46580

September 11, 1989

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No. 89-243

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY

Petitioner,

U.

MEDTRONIC, INC.,

Respondent.

**MOTION AND BRIEF FOR AMICI CURIAE
SENATOR ORRIN G. HATCH AND
REPRESENTATIVE CARLOS J. MOORHEAD
IN SUPPORT OF THE PETITION FOR A WRIT
OF CERTIORARI TO THE UNITED STATES COURT
OF APPEALS FOR THE FEDERAL CIRCUIT**

PETER BARTON HUTT
Counsel of Record
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue NW
P.O. Box 7566
Washington, D.C. 20044
202/662-5522

Counsel for Amici Curiae

10 pp

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**MOTION OF AMICI CURIAE SENATOR ORRIN
G. HATCH AND REPRESENTATIVE CARLOS
J. MOORHEAD FOR LEAVE TO FILE THE
ACCOMPANYING BRIEF AMICI CURIAE IN
SUPPORT OF THE PETITION FOR CERTIORARI**

Pursuant to Rule 36.1 of this Court, *amici curiae*, the Honorable Senator Orrin G. Hatch and the Honorable Representative Carlos J. Moorhead, respectfully move this Court for leave to file the attached brief of *amici curiae* in support of the petition for certiorari. Movants have been unable to secure the

consent of the respondent.¹

This case involves the statutory construction of 35 U.S.C. § 271(e)(1). Senator Orrin G. Hatch was the principal, if not sole, author of the legislation that was enacted into law as Section 271(e)(1). Representative Carlos J. Moorhead was the primary manager of the same legislation on the floor of the House of Representatives. The *amici curiae* have a heightened interest in having the courts properly construe Section 271(e)(1) in accordance with the Congressional intent set forth in the plain language and legislative history of the statute.

Amici curiae believe that their views will be helpful to the Court in understanding the legislative history of Section 271(e)(1) and emphasizing the importance of this case to U.S. industries involving medical devices, food additives, color additives, and other nondrug, FDA-regulated products. *Amici curiae* also believe that their views will aid the Court by addressing the legislative history of Section 271(e)(1) in detail greater than that discussed by the petitioner.

Respectfully submitted,

Dated: September 11, 1989

PETER BARTON HUTT

Counsel of Record

ELLEN J. FLANNERY

COVINGTON & BURLING

1201 Pennsylvania Avenue NW

Washington, D.C. 20044

202/662-5522

Counsel for Amici Curiae

¹ *Amici curiae* obtained the consent of the petitioner to file their brief. On Friday, September 8, 1989, *amici curiae* attempted to obtain the consent of the respondent Medtronic, Inc. pursuant to Rule 36.1 of this Court. However, respondent through its counsel declined to give its consent, and stated that respondent wanted to review the brief before it considered giving its consent.

Amici curiae informed respondent's counsel that they could not comply with respondent's request due to the time constraints and approaching deadline for the filing of briefs of *amicus curiae* in this action. Respondent's counsel then stated that its client was unavailable to authorize consent. Therefore, this motion became necessary.

QUESTION PRESENTED

Amici curiae, Senator Orrin G. Hatch and Representative Carlos J. Moorhead, adopt the following question presented by petitioner Eli Lilly and Company.

35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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35 U.S.C. § 271(e)(1) *passim*

Legislative History:

H.R. Rep. No. 857, 98th Cong., 2d Sess., Parts 1 and 2,
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UNITED STATES COURT OF APPEALS FOR
THE FEDERAL CIRCUIT**

The Honorable Senator Orrin G. Hatch and Honorable Representative Carlos J. Moorhead submit this brief of *amici curiae* in support of the petition for certiorari in the above-identified case.

INTEREST OF THE AMICI CURIAE

Senator Orrin G. Hatch was the principal, if not sole, author of the Senate Bill which ultimately was enacted into law as 35 U.S.C. § 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984. At that time, Senator Hatch was Chairman of the Senate Committee on Labor and Human Resources and a member of the Senate Judiciary Committee. Representative Carlos J. Moorhead was the primary manager of the legislation enacting Section 271(e)(1) on the floor of the House of Representatives. At that time in 1984, Representative Moorhead was the Ranking Republican of the Subcommittee on Courts, Intellectual Property and the Administration of Justice that processed the legislation.

It is respectfully submitted that the Court of Appeals' decision, dated March 29, 1989, should be set aside since it misinterpreted the narrow infringement exemption of Section 271(e)(1) enacted by Congress. Senator Hatch and Representative Moorhead have an interest in having the courts properly construe federal statutes in accordance with Congressional intent set forth in the plain language and legislative history of the statute. This interest is heightened with respect to Section 271(e)(1) since both were involved actively in its passage.

Amici curiae desire to maintain the separation of powers between the judicial and legislative branches of government. The Court of Appeals' decision violates the separation of powers doctrine by taking patent rights from patent holders of inventions for medical devices, food additives, and color additives. Congress did not enact Section 271(e)(1) as the Court of Appeals has construed it.

ARGUMENT

In the view of the *amici curiae*, the Court will benefit from an understanding of the true intent of Congress as set forth in the legislative history of Section 271(e)(1). The purpose behind the enactment of Section 271(e) was to overrule the narrow aspect of the holding—denying a non-licensee use of a patented drug product, prior to the patent's expiration, for purposes related to obtaining FDA approval for a generic substitute to be sold only

after the patent expires—by the Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). That narrow holding was seen as specifically limited to human drug testing. It is explained by the Court of Appeals itself as follows:

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

Roche, 733 F.2d at 861.

Congress intended to restrict the infringement exemption exclusively to this narrow holding of *Roche* limited to human drugs. Congress included the language "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added).

It was never the intention of Congress to overrule *Roche* with respect to anything other than human drugs with Section 271(e)(1) as enacted in 1984. Congress' intent to limit its reversal of *Roche* to the narrow drug issue before the Court in *Roche* is expressed in the legislative history:

In Section 202, Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information *for the purpose of obtaining FDA pre-marketing approval of a drug*. The purpose of the provision is to overturn the ruling in *Roche* That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the FDA for the purpose of enabling Bolar to market the drug after the patent expired.

H.R. Rep. No. 857, 98th Congress, 2nd Sess., Pt.2 at 27, *reprinted in* 1984 U.S. Code and Cong. & Administrative News 2647, 2711,

fn. 18 (1984) (opinion of the Library of Congress, American Law Division) (emphasis added).

The Congressional understanding that the holding of *Roche* was specifically drug-oriented is further supported in the following legislative commentary:

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.

In *Roche* . . . the Court of Appeals for the Federal Circuit held that experimental use of a *drug product* prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.

Id. at 2678-2679 (emphasis added).

When Congress considered whether Section 271(e)(1) eroded these exclusive rights with respect to drug patents, it was very concerned about the potential unconstitutional "taking" that might result if the law was too broad. The Committee on the Judiciary rejected the constitutional attack chiefly because the law was limited to drug testing:

First, the *only* activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt 2, at 8, *reprinted in* 1984 U.S. Code Cong. & Admin. New 2647, 2692 (1984) (emphasis added).

In 1988, when Congress decided to add similar limited infringement exemptions for veterinary biological products, it did so by express language through an amendment to Section 271(e). See Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988).

More recently, the Honorable Senator Dennis DeConcini has introduced Senate Bill S.622 in 1989. This Bill proposes to add the term "medical device" to Section 271(e)(1), as well as to several additional portions of Section 271(e). These instances of product-specific additions are further examples that it was never Congress' intent in the 1984 Act (as amended in 1988) to include "medical devices" within the infringement exemption of Section 271(e)(1).

Respectfully submitted,

PETER BARTON HUTT

Counsel of Record

ELLEN J. FLANNERY

COVINGTON & BURLING

1201 Pennsylvania Avenue NW

P.O. Box 7566

Washington, D.C. 20044

202/662-5522

Counsel for Amici Curiae

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No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
v. *Petitioner,*
MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND
BRIEF IN SUPPORT OF PETITION ON BEHALF OF
PFIZER HOSPITAL PRODUCTS GROUP, INC. AND
PFIZER INC. AS *AMICI CURIAE*

Of Counsel:

PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd St.
New York, New York 10017

RUDOLF E. HUTZ
CONNOLLY, BOVE, LODGE
& HUTZ
1220 Market Street
Wilmington, Delaware 19899
Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.

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On Petition for a Writ of Certiorari to the
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**MOTION FOR LEAVE TO FILE BRIEF IN SUPPORT
OF PETITION ON BEHALF OF PFIZER HOSPITAL
PRODUCTS GROUP INC. AND PFIZER INC.
AS *AMICI CURIAE***

Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") respectfully move this Court, pursuant to Rules 36.1 and 42 of the Rules of the Supreme Court, for leave to file the attached brief as *amici curiae* in the above-captioned case. Pfizer's brief is in support of the Petitioner, and urges that this Court review and reverse the decision below.

Counsel for Petitioner, Eli Lilly and Company ("Lilly"), have consented in writing to the filing of an *amici* brief by Pfizer. No unqualified consent of the Respondent,

Medtronic, Inc., could be obtained, thereby necessitating this motion.

Pfizer Hospital Products Group, Inc. is a research-based manufacturer of medical devices and Pfizer Inc. is its parent organization. Pfizer has been engaged for years in research, development and sale of medical devices and drugs designed to alleviate and cure various conditions destructive of the health of mankind.

The subject Petition of Lilly addresses a decision by the Court of Appeals for the Federal Circuit which held that the infringement exemption set forth in 35 U.S.C. § 271(e)(1) applies to medical devices as well as to drugs and veterinary biological products. Unlicensed use and sale of medical devices were thereby authorized. Pfizer believes that the decision was erroneous and based upon a mistaken perception of the nature of the holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), and what the Congress was seeking to accomplish in reversing that holding.

Pfizer possesses a unique historical perspective as an innovator and marketer of both medical devices and drugs. Pfizer believes that this perspective and its experience in day-to-day dealings with the applicable Federal Laws governing sale of these products will assist the Court in better understanding the competing policies and statutory compromises intended by Congress when it enacted the Drug Price Competition and Patent Term Restoration Act of 1984, which the Federal Circuit erroneously interpreted below.

As shown in the attached Brief, the issue decided by the Federal Circuit affects far more than the individual interests of the named parties. The decision below, which holds that the statutory words "drugs or veterinary biological products" include medical devices, adversely impacts on innovation in the medical device industry to the

direct detriment of the public interest. Patents directed to a wide variety of lifesaving and quality of life-enhancing devices are now relegated to a second-class and partially unenforceable status.

Given the Constitution, it is questionable whether Congress could have by law restricted a patent owner's rights as occurred below. Most certainly, however, the rights possessed by owners of medical device patents cannot be taken away under the guise of statutory interpretation in the face of clear, contrary statutory language and congressional intent.

Pfizer respectfully requests that the Court permit it to file the attached brief and that Petitioner's request to issue a writ of certiorari to review the judgment and opinion of the Federal Circuit be granted.

Respectfully submitted,

Of Counsel:

PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd St.
New York, New York 10017

RUDOLF E. HUTZ
CONNOLLY, BOVE, LODGE
& HUTZ
1220 Market Street
Wilmington, Delaware 19899
*Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.*

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-243

ELI LILLY AND COMPANY,
v. *Petitioner*,
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Respondent.

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for the Federal Circuit

BRIEF FOR PFIZER HOSPITAL PRODUCTS
GROUP, INC. AND PFIZER INC. AS *AMICI CURIAE*

INTEREST OF *AMICI*

Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") are research-based manufacturers of medical devices and drugs. For many years, Pfizer has conducted research and development into such products for which it has received hundreds of United States Patents.

As an innovator and seller of new medical devices and drugs, Pfizer is thoroughly familiar with both the enormous costs required to develop such products and the expensive approval and marketing requirements of Federal Law. Pfizer has participated in the regulatory ap-

proval process since well before Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act") which is at issue here.

As a substantial patent owner, Pfizer recognizes the incentives offered by the United States patent system in return for research expenditures and innovation into the cure and alleviation of conditions destructive to the health and well being of man. The decision below affects far more than the named parties. By deciding that the statutory words "drugs or veterinary biological products" include medical devices, the Federal Circuit has rendered patents to such devices partially unenforceable. Patents directed to a wide variety of lifesaving and quality of life-enhancing devices can now be practiced without the owner's consent, thereby reducing the reward and hence the incentive to undertake the enormous expense to develop and market new products.

Pfizer believes that the full scope of patents to medical devices should be restored by this Court. Given the Federal Circuit's exclusive jurisdiction (28 U.S.C. § 1295), no other judicial forum is available to achieve this objective.

ARGUMENT

The Petition should be granted here because the decision below significantly impedes the availability of new medical devices, and it is based on a misreading of congressional intent as well as the decision, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) ("*Roche*"), which Congress overruled when it enacted 35 U.S.C. § 271(e)(1). The 1984 Act simply does not say what the Federal circuit claims it does, and the intent of the Congress belies the court's legally erroneous interpretation.

I. THE HOLDING IN *ROCHE* v. *BOLAR*, WHICH CONGRESS REVERSED BY ENACTING 35 U.S.C. § 271(e)(1), WAS LIMITED TO PATENTED DRUG INVENTIONS

A significant portion of the Federal Circuit's decision was devoted to an effort to identify the precise holding in *Roche*. This was because the court quite correctly accepted the following as an explicit statement of congressional intent: -

"The provisions of section 202 of the bill [i.e., the amendment of Title 35 adding section 271(e)(1)] have the net effect of reversing the holding of the court in *Roche*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2 at 27, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2711 (Pet. App. 6a)¹

The Federal Circuit also properly stated that:

". . . what is clear to this court, as well as to the parties and the district court, is that section 271(e)(1) was added to overrule this court's decision in *Roche*." (Pet. App. 5a)

In section IV of its opinion (Pet. App. 5a-6a), the court below announced its interpretation of the *Roche* holding. In so doing, not one single word from the *Roche* decision was quoted. The court completely ignored the following clear and certain statement of the holding in *Roche*:

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented *drug* for testing and investigation strictly related to FDA *drug* approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The district court held that it does not. This was an error of law. *Roche*, 733 F.2d at 861 (emphasis added)

¹ "Pet. App." refers to the Appendix filed by Petitioner, Eli Lilly and Company.

As the legislative history makes readily apparent, this is the precise *holding* (as distinguished from *underlying rationale* and *dicta*) which Congress overruled when enacting 35 U.S.C. § 271(e)(1).

Nothing in *Roche* supports the Federal Circuit's conclusion that the *Roche holding* extended to *all* patented inventions related to products subject to regulatory approval under the Federal Food, Drug and Cosmetic Act (i.e., drugs, medical devices, food additives, color additives, etc.). By enacting 35 U.S.C. § 271(e)(1), Congress did not intend, as the court below implied, to overrule over one hundred fifty years of federal court jurisprudence dating back to *Whittemore v. Cutter*, 29 F.Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) on the experimental use defense to liability for infringement. Only a complete misreading of the holding in *Roche* and congressional intent could have led the court to arrive at such an erroneous conclusion.

II. CONTRARY TO THE FEDERAL CIRCUIT'S ASSERTION, PERSUASIVE REASONS DID EXIST FOR CONGRESS' FAILURE TO EXTEND 35 U.S.C. § 271(e)(1) TO MEDICAL DEVICES

The lower court's decision was heavily influenced by the fact that the 1984 Act, which included the new 35 U.S.C. § 271(e)(1), also provided for patent term restoration for drugs, medical devices, food additives and color additives. Following a discussion of statutory construction, the court came to the erroneous conclusion that the only way to make sense out of the 1984 Act was to assume that Congress intended 35 U.S.C. § 271(e)(1) to apply to medical devices, and presumably also food additives and color additives, as well as to drugs (Pet. App. 7a).

In reaching this conclusion, the court cited no legislative history whatsoever and it failed to recognize that the 1984 Act was based upon a desire to promote two sig-

nificant congressional policies. Neither of these policies *per se* involved overruling *Roche*. First, the 1984 Act contained provisions for patent term restoration for drugs, medical devices, food additives and color additives. Second, the 1984 Act included abbreviated testing procedures for regulatory approval of generic substitutes for patented drugs so that generic drug substitutes could be marketed promptly after expiration of patents covering the drug. These provisions for expedited marketing of generic substitutes applied to drug products *only*. There were no comparable provisions for abbreviated testing for "generic" medical devices.² Under the *Roche* holding, the abbreviated testing procedures for generic drug substitutes constituted patent infringement, and so Congress had to make a very limited exception to the law of infringement to carry forward its second policy objective.

Without question, Congress intended 35 U.S.C. § 271(e)(1) to apply to drugs only because Congress, in enacting the 1984 Act, reasoned as follows: (1) patent term restoration for drugs, medical devices, food additives and color additives was, in and of itself, desirable; (2) abbreviated testing procedures for generic substitutes of patented drugs to permit the marketing of such generic drug substitutes promptly after patent expiration was also desirable; and (3) in order to realize objective (2), 35 U.S.C. § 271 had to be amended (as in 35 U.S.C. § 271(e)(1)) for patented *drug* inventions only.

² The legislative history of the 1984 Act shows no significant input by the manufacturers of "generic" medical devices.

CONCLUSION

The decision of the Federal Circuit below, in an area where it has no special expertise, is a clear error of law. It will have an adverse impact on companies which innovate, develop, and market medical devices, and consequently on those who would use and benefit from such devices. The impact extends far beyond the parties to this case. Patent owners in this field now hold patents which cannot be enforced against unlicensed use, even though the unlicensed users reap significant benefits, both economically and business-wise.

This disincentive to innovation arises from a plain error in statutory construction. This clear error of law should be corrected by this Court.

Respectfully submitted,

Of Counsel:

PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd St.
New York, New York 10017

RUDOLF E. HUTZ
CONNOLLY, BOVE, LODGE
& HUTZ
1220 Market Street
Wilmington, Delaware 19899
Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.

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MOTION AND BRIEF OF AMICUS CURIAE
INTELLECTUAL PROPERTY OWNERS, INC.
IN SUPPORT OF THE PETITIONER

DONALD W. BANNER
HERBERT C. WAMSLEY *
INTELLECTUAL PROPERTY
OWNERS, INC.
1255 Twenty-Third Street, N.W.
Suite 850
Washington, D.C. 20037
(202) 466-2396
Attorneys for Amicus Curiae

September 11, 1989

* Counsel of Record

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MOTION OF AMICUS CURIAE
INTELLECTUAL PROPERTY OWNERS, INC.
IN SUPPORT OF THE PETITIONER

Intellectual Property Owners, Inc. ("IPO") moves this court for leave to file the accompanying brief *amicus curiae* in support of the petition for certiorari. IPO has been unable to obtain the consent of the respondent pursuant to rule 36.1.¹

IPO is a broadly based association with members in nearly all major industries. IPO's members manufacture

¹ Counsel for respondent advised that respondent would not give its consent without an opportunity to review the proposed brief *amicus curiae*. IPO was unable to follow such a procedure within the time permitted by the rules of this Court for filing the brief.

several other types of products that could be affected by the decision of the Court of Appeals by the Federal Circuit besides the medical devices that are in dispute between the petitioner and the respondent. The Court of Appeals decision may affect patent rights in the areas of food additives, color additives, agricultural chemicals, and other nondrug products that are subject to regulation by the federal government or that may be subject to government regulation in the future.

IPO believes the information and views presented in its proposed brief would be useful to the Court as a supplement to the petition for certiorari. IPO's proposed brief emphasizes the broad national impact of this case and its potential impact on several industries. IPO's proposed brief presents facts relating to the intent of Congress in modifying the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) that go beyond the facts presented in the petition for certiorari filed by Eli Lilly and Company.

IPO believes its proposed brief will assist the Court in understanding why this case may affect the international competitiveness of U.S. industry.

Respectfully submitted,

DONALD W. BANNER
HERBERT C. WAMSLEY *
INTELLECTUAL PROPERTY
OWNERS, INC.
1255 Twenty-Third Street, N.W.
Suite 850
Washington, D.C. 20037
(202) 466-2396
Attorneys for Amicus Curiae

* Counsel of Record

September 11, 1989

QUESTION PRESENTED

Amicus curiae, Intellectual Property Owners, Inc. ("IPO"), adopts the question presented by petitioner Eli Lilly and Company, which is enclosed in quotation marks below, *except* that IPO would replace "FDA-regulated" in the last sentence below with "federally regulated" because IPO believes the Court of Appeals may have expanded the patent infringement exemption even beyond FDA-regulated products:

"35 U.S.C. § 271(e)(1) provides that 'it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*' (emphasis added).

"The question presented is:

"Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond 'drugs' and 'veterinary biological products' to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?"

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BRIEF OF AMICUS CURIAE
INTELLECTUAL PROPERTY OWNERS, INC.
IN SUPPORT OF THE PETITIONER

INTEREST OF THE AMICUS CURIAE

Intellectual Property Owners, Inc. ("IPO") files this *amicus curiae* brief in support of the petition of Eli Lilly and Company for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered on March 29, 1989.

IPO was founded in 1972 by a group of individuals who were concerned about the lack of understanding of intellectual property rights in the United States. Members include nearly one hundred large and medium size companies and some smaller businesses and independent inventors who own patents and other intellectual property

rights. Members of IPO's Board of Directors are listed in the appendix to this brief. IPO is a nonprofit association exempt from federal income tax under Internal Revenue Code § 501(c)(6).

IPO conducts a government relations program in Washington, D.C. IPO supports legislation to strengthen protection available under the U.S. patent, trademark, copyright, and trade secret laws. Enactment of such legislation helps IPO's members and strengthens incentives for innovation and investment in the United States, improving the country's industrial competitiveness.

The Court of Appeals decision may erode patent rights not only in the area of medical devices, but also in the areas of food additives, color additives, agricultural chemicals, and other nondrug products that are subject to regulation by the federal government or may be subject to federal regulation in the future. This may weaken U.S. patent protection for IPO members, contrary to IPO's commitment to advocating strong rights in patents. IPO seeks to safeguard the full measure of the patent system that gives vital incentives for technological innovation, creativity and business investment.

ARGUMENT

I. AN IMPORTANT FEDERAL STATUTORY ISSUE SUBSTANTIALLY AFFECTING PATENT RIGHTS IS BEFORE THIS COURT

The possible ramifications of the Court of Appeals' decision are widespread. For the first time, otherwise-infringing competitors of the patent holder will be able to make, use, and sell patented medical devices during clinical trials before a patent expires. Otherwise-infringing competitors of the patent holder in the food and color additive industries, the agricultural chemical industry, and other industries also may be able to make, use, and sell patented inventions to obtain federal regulatory ap-

proval before the patent expires. This outcome may offer copiers a competitive advantage even though they did not undertake the substantial risk and expense in inventing and then establishing the commercial value of the inventions.¹

In effect, the Court of Appeals decision may discourage that which the patent laws are intended to encourage—innovation, technological development, and investment in high-risk ventures. The decision may encourage copying instead, and weaken U.S. patent protection for nondrug, federally-regulated products.

II. CERTIORARI IS NECESSARY TO REVIEW THE ANALYSIS BY THE COURT OF APPEALS BECAUSE OF THE BROAD IMPACT ON THE PATENT SYSTEM AND SEVERAL INDUSTRIES

The Court of Appeals concluded that "ambiguous language" in the statute and "ambiguous statements in the legislative history" support inclusion of at least medical devices, food additives and color additives within the infringement exemption of 35 U.S.C. § 271(e)(1). See Pet. App. 5a.² The Court of Appeals apparently rejected or failed to consider several grounds relied upon by the District Court for limiting § 271(e)(1) to its plain language, which says the infringement exemption covers drugs and certain veterinary biological products.

The opinion by Circuit Judge Newman dissenting from the denial of a rehearing *en banc* (Pet. App. 10a) high-

¹ There are reasons for distinguishing between drugs and nondrug, FDA-regulated products. Lilly's petition for certiorari sets forth the reasons, and they will not be repeated here. See Petition for Writ of Certiorari, pp. 14-18. As explained in this brief, IPO believes the Court of Appeals decision may also have ramifications for products regulated by agencies other than FDA.

² "Pet. App. 5a" refers to page 5a of petitioner's appendix. IPO will refer to petitioner's appendix on other occasions using the same citation form.

lights the incomplete nature of the analysis by the Court of Appeals. Judge Newman summarized the District Court opinion as follows:

The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set forth in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs.

Pet. App. 11a.

The opinion by the Court of Appeals did not analyze the arguments considered by the District Court. Instead, the Court of Appeals adopted an extraordinary interpretation of how Congress, when it enacted § 271(e)(1), intended to alter the impact of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984). According to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all of its ramifications" and allow a party to "make, use or sell any type of 'patented invention'" (Pet. App. 7a, emphasis in the original), provided the patented invention was used for the purpose of developing information to submit to a federal regulatory agency. IPO agrees with the petitioner that this interpretation is clearly in error. Petition for writ of certiorari, p. 13.

In *Roche*, the Federal Circuit interpreted § 271(a) as providing that it is infringing activity for a party to make, use or sell any patented invention for the purposes of developing information to submit to a federal regulatory agency. Congress in 1984 overruled *Roche* only with

respect to "drugs", whatever it meant by the term "drugs". Congress certainly did not intend to overrule the *Roche* interpretation of § 271(a) with respect to all patented inventions.

The 1984 version of § 271(e)(1) stated explicitly that it did not extend to an "animal drug or veterinary biological product". Moreover, when § 271(e)(1) was enacted Congress also had before it somewhat similar proposals affecting patent rights in agricultural chemicals regulated by the Environmental Protection Agency.³ Apparently neither petitioner nor respondent believes Congress overruled the *Roche* interpretation of § 271(a) as it affects agricultural chemicals regulated by EPA. See petition for writ of certiorari, n.12. The petitioner presents the question as whether the Court of Appeals has expanded the patent infringement exemption to all FDA-regulated products.

IPO notes, however, that the Court of Appeals opinion, if read literally, would extend the reach of § 271(e)(1) even beyond FDA-regulated products, to agricultural chemicals and all other types of patented inventions regulated by any federal agency. The language in § 271(e)(1) does not limit the section to FDA-regulated, patented inventions. It covers "... uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products" (emphasis added).

Most recently, the 1988 amendment to § 271(e)(1), which extended coverage to certain veterinary biological

³ E.g., H.R. 5529, 98th Cong., 2d Sess. Congress subsequently has considered several other bills affecting patent rights in agricultural chemicals. Some of these bills have proposed to amend § 271(e) to refer specifically to agricultural chemicals. E.g., S. 1516, 100th Cong., 1st Sess., § 2402, p. 167 (amendment to 35 U.S.C. § 271(e) covering pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act).

products, explicitly excluded biotechnology-related animal drugs and veterinary biological products, making clear again that the section does not cover all patented inventions.⁴

The Court of Appeals was mistaken in believing § 271 (e) (1) covers all types of patented inventions. This erroneous belief was the foundation for the court's entire opinion. As pointed out by Judge Newman, the Court of Appeals was legislating. Judge Newman observed that Congress, not the court, is empowered to legislate in matters affecting patent rights. (Newman dissent, reproduced at Pet. App. 13a, citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567 (1886)).

⁴ The 1988 amendment of § 271(e)(1), expanding the section to cover certain veterinary biological products, includes subject matter regulated by the Secretary of Agriculture under the Virus-Serum-Toxin Act. See Pub. L. No. 100-670, Title II, "Patent Terms". Thus, § 271(e)(1) covers some subject matter not regulated by FDA.

CONCLUSION

The decision of the Court of Appeals could well have a negative impact on patent protection for innovators of medical devices, food additives, color additives, agricultural chemicals, and any other types of inventions that are regulated by the federal government or that might be regulated in the future. A grant of certiorari is respectfully requested to review the analysis of § 271(e)(1) by the Court of Appeals on this vital issue of national importance.

Respectfully submitted,

DONALD W. BANNER
HERBERT C. WAMSLEY *
INTELLECTUAL PROPERTY
OWNERS, INC.

1255 Twenty-Third Street, N.W.
Suite 850
Washington, D.C. 20037
(202) 466-2396

Attorneys for Amicus Curiae

* Counsel of Record

September 11, 1989

APPENDIX

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Kalamazoo, MI

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Attorney
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Pittsburgh, PA

10
No. 89-243

Supreme Court, U.S.
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**In the
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

JOINT APPENDIX

TIMOTHY J. MALLOY
Counsel of Record
GREGORY J. VOGLER
LAWRENCE M. JARVIS
McANDREWS, HELD & MALLOY, LTD.
Northwestern Atrium Center
500 West Madison Street
Chicago, Illinois 60606
312/707-8889
Counsel for Petitioner

JOHN F. LYNCH
Counsel of Record
W. BRYAN FARNEY
ARNOLD, WHITE & DURKEE
P.O. Box 4433
Houston, Texas 77210
713/787-1400
Counsel for Respondent

***Petition for Certiorari Filed August 11, 1989
Certiorari Granted October 10, 1989***

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**RELEVANT DOCKET ENTRIES
DISTRICT COURT**

**PLAINTIFF
ELI LILLY AND
COMPANY**

**DEFENDANT
MEDTRONIC, INC.**

		DOCKET NO. 83-5393
DATE	NR	PROCEEDINGS
11/7/83	1	Complaint filed
11/7/83		Jury Trial Demanded
1/9/84	8	Answer of Hahnemann University to complaint and counterclaim, filed.
1/26/84	10	Order dated 1/25/84 that the attached Stipulation and Notice of Dismissal is approved except that paragraph one shall be interpreted only as a recognition between parties that jurisdiction and venue are proper, and not as a judicial determination of either. Deft. Medtronic's motion to dismiss for improper venue is denied, filed. 1/26/84 entered & copies mailed.
2/16/84	11	Medtronic's answer to complaint and counterclaim, filed.
7/9/84	19	Order that pltf's motion to strike defenses from answer and counterclaim is granted in part and denied in part, etc., filed. 7/10/84 entered & copies mailed.
8/3/84	20	Pltf's reply to deft's counterclaim, filed.
1/8/86	24	Order that deft's motion for summary judgment is denied, filed. 1/9/86 entered & copies mailed.

1/10/86	31	Order that all further discovery and proceedings in this litigation are stayed pending a final decision by the U.S. Patent & Trademark Office, etc., filed. 1/10/86 entered & copies mailed.
5/5/87	40	Order that Lilly is hereby substituted for Intec as pltf in this action, filed. 5/5/87 entered & copies mailed.
7/8/87	47	Pltf's brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused, filed. (FILED UNDER SEAL)
7/8/87	48	Pltf's brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused, filed. (FILED UNDER SEAL)
7/8/87	49	Medtronic's memorandum regarding the application of 35 U.S.C. § 271(e)(1) to investigational medical devices, cert of service, filed.
7/13/87	50	Pltf's reply brief in opposition to deft's suggestion that otherwise infringing manufacture, use and sale of its cardioverters and defibrillators are excused. 35 U.S.C. § 271(e)(1), cert of service, filed.
7/13/87	51	Medtronic's reply to Lilly's brief regarding 35 U.S.C. § 271(e)(1), filed. (FILED UNDER SEAL)
11/12/87	72	Pltf's supplemental brief in support of its position on non-applicability of 35 U.S.C. § 271(e)(1) to the actions of deft, filed. (FILED UNDER SEAL)

11/13/87	73	Reply of Medtronic to pltf's supplemental brief in support of its position on 35 U.S.C. § 271(e)(1), cert of service, filed.
11/19/87	84	Motion of deft Medtronic, Inc. for a pre-trial order on the applicability of 35 U.S.C. § 271(e)(1) to medical devices or in the alternative for partial summary judgment, cert of service, filed.
12/8/87	92	Memorandum & Order that deft Medtronic, Inc.'s motion for partial summary judgment is denied, deft is precluded from presenting at trial evidence regarding the 271(e)(1) defense, filed. 12/8/87 entered & copies mailed.
12/11/87	97	Motion of deft Medtronic, Inc. for certification of the Section 271(e)(1) issue for appeal, cert of service, filed.
12/18/87	99	Order that deft Medtronic, Inc.'s motion for certification of the Section 271(e)(1) issue as decided by this Court in its memorandum & order of 12/4/87 is denied, filed. 12/18/87 entered & copies mailed.
1/4/88	109	Deft Medtronic's pre-trial brief, filed. (FILED UNDER SEAL).
2/9/88	123	Deft Medtronic's pre-trial brief, filed. (FILED UNDER SEAL).
2/10/88	130	Plff's pretrial brief in support of its damage presentation, filed. (FILED UNDER SEAL).
2/10/88	131	Pltf's pretrial brief in support of injunction, filed (FILED UNDER SEAL)
2/10/88	132	Plff's pretrial overview of the case, filed (FILED UNDER SEAL)

2/24/88	160	Civil Jury Trial of 2/23/88, day 1, jurors called and sworn, plff opens, defense opens, plff witness sworn, filed.
2/25/88	161	Civil Jury Trial of 2/24/88, day 2, plff witnesses recalled, witness sworn, filed.
2/26/88	165	Civil Jury Trial of 2/25/88, day 3, plff witness recalled, plff deposition testimony, filed.
2/29/88	166	Civil Jury Trial of 2/26/88, plff witness' sworn, filed.
3/1/88	170	Civil Jury Trial of 2/29/88, jurors present, plff witness testifies, filed.
3/2/88	171	Trial resumes 3/1/88, Pltf's Witnesses sworn, filed.
3/4/88	173	Trial resumes 3/3/88, jurors present, pltf's witness sworn, plff deposition of Michael Kalluk read to jury, defense counsel moves the Court for a directive verdict refused by Court, defense witness sworn, filed.
3/4/88	174	Trial resumes 3/4/88, defense witness recalled, defense witness sworn & recalled, filed.
3/8/88	175	Trial resumes of 3/7/88, etc, filed.
3/8/88	176	Supplemental Report of Special Master filed.
3/10/88	179	Trial resumes 3/9/88; defense counsel moves for a mistrial - C.A.V., etc., filed.
3/11/88	183	Trial resumes 3/10/88, filed.
3/14/88	186	Jury trial resumes 3/11/88; Deft's motions for a mistrial is hereby refused by the Court, etc., filed.

3/14/88	187	Deft's Memo re: Revised Proposed Jury Instructions; Objections to Certain Lilly Instructions; & Responses to Lilly's objections, filed.
3/15/88	188	Trial resumes of 3/14/88, filed.
3/16/88	189	Jury trial resumes of 3/15/88, filed.
3/16/88	190	Medtronic's further objections & comments with respect to Lilly's revised proposed jury instructions, filed.
3/16/88	193	Trial resumes 3/16/88; Deft's move for Directed Verdict - Court ruled - Motion is hereby refused, filed.
3/16/88	196	Plaintiff's brief in support of injunction during extension of the '757 patent, filed.
3/22/88	201	Special Interrogatories to the Jury, filed.
3/22/88	202	Trial resumes 3/21/88; Court charges Jury, filed.
3/23/88	204	Trial resumes 3/22/88, filed.

3/24/88	205	Trial resumes 3/23/88, deliberations continue. Verdict in favor of plttf & against the deft in the amount of \$26.5 million per Special Interrogatories to the jurors, filed.
3/24/88	206	Special Interrogatories to the Jury & Answers, thereof, filed.
3/25/89	208	Argued Sur 3/25/88 re defendant Medtronic post trial brief on issue of inequitable conduct and plaintiff response for injunction relief, C.A.V., filed.
3/25/88	213	Memo in opposition to Injunctive Relief, filed.
4/1/88	218-240	Transcripts of Jury Trial, filed. (23 Vols.)
4/4/88	241	Order that deft's motion for mistrial is hereby refused & in explanation of the order, filed. 4/4/88 entered and copies mailed.
4/18/88	244	Argued Sur: Hearing on 4/15/88 re: Plttf's request for injunctive relief is granted. Order will be filed.
4/18/89	245	Defendant's objections to proposed form of injunction, cert. of serv., filed.
3/19/88	246	Plttf's Posttrial Memo Regarding Enforceability of Patents in Suit, filed.
4/19/89	247	Plaintiff's post trial brief in support of injunction, cert. of serv., filed.
4/20/88	248	Plttf's brief in support of increased damages, cert of serv, filed.
4/21/89	249	Plaintiff's response to Medtronic's objections to proposed form of injunction, cert. of serv., filed.

4/21/88	250	Plttf's brief in support of an award of attny fees & expenses pursuant to 35 U.S.C. Section 285, cert of serv, filed.
4/21/89	251	Plaintiff's brief in support of prejudgment interest, cert. of serv., filed.
4/21/88	252	Memo & order that US Patents No. 27,757, reexamined & issued as B1 Re. 27,757, No. 3,942,536, reexamined & issued as B1 3,942,536 are valid and enforceable: judgment is hereby entered in favor of plttf Eli Lilly & Co. & against deft Medtronic, Inc. in the amt of \$26,500,000, plus an additional royalty of \$166,000 totalling \$26,666,000, filed. 4/21/88 entered and copies mailed.
4/21/88	253	Order that having made findings of fact & reached conclusions of law of record on 4/15/88 and having concluded on 4/21/88, there was no inequitable conduct, the motion of Eli Lilly & Co. for injunctive relief against deft Medtronic, Inc. is granted, filed. 4/21/88 entered & copies mailed.
4/22/88	254	Defendant Medtronic's motion for stay of this court's injunction pending appeal, Memo, cert. of serv., filed.
4/27/88	256	Plaintiff's brief in opposition to defendant's Motion to Stay Injunctive Relief, cert. of serv., filed.
5/2/88	265	Transcript of Court's Findings of Fact & Conclusions on 4/15/88, filed.
5/3/88	266	Order that deft Medtronic, Inc.'s motion for stay pending appeal of Court's injunction entered 4/21/88 is denied, filed. 5/4/88 entered and copies mailed.

5/5/88	267	Medtronic's motion for judgment notwithstanding the verdict as to Claim 4 of U.S. Patent Re. 27,757, memo, cert of serv, filed.
5/5/88	268	Medtronic's motion for judgment notwithstanding the verdict on the question of willful infringement, memo, cert of serv, filed.
5/5/88	269	Medtronic's motion pursuant to Rule 62(B) to stay execution of judgment pending disposition of post-trial motions, memo, cert of serv, filed.
5/5/88	270	Medtronic's motion under Rule 50(B) for judgment of reduced damages notwithstanding the verdict, memo, cert of serv, filed.
5/5/88	271	Medtronic's motion for a new trial, memo, cert of serv, filed.
5/5/88	272	Medtronic's contingent motion for a stay of execution of judgment pending appeal, memo, cert of serv, filed.
5/12/88	275	Deft's notice of appeal sent to Federal Circuit Court of Appeals, filed. 5/13/88 copies: R. Schneider, Esq., H. Jacobson, Jr., Timothy Malloy, Esq., Clerk, USCA, Judge Ditter, D. Spitz.
5/12/88	275(a)	Copy of Clerk's Notice to Federal Circuit Court of Appeals, filed. (USCA Fed Cir. #88-1409)
6/23/88	288	Order that Defendant Medtronic's, Inc.'s unopposed motion to stay execution of judgment pending disposition of post-trial motions is granted. Judgment contained in Court's 4/21/88 order stayed pending disposition of all pending motions under Rule 50, 52(B) and 59 filed, filed.

4/3/89	305	Defendant Medtronic's Motion to Clarify or stay the injunction of 4/21/88, memo, cert. of serv., filed.
4/6/89	306	Errata sheet for Medtronic's memo in support of motion to clarify or stay the injunction of 4/21/88, filed.
4/11/89	307	Lilly's Memo in opposition to Medtronic's Motion to clarify or stay the injunction of 4/21/88, cert. of serv., filed.
4/13/89	308	Plaintiff's supplemental brief in opposition to Medtronic's motion to clarify or stay the permanent injunction, cert. of serv., filed.
4/14/89	309	Hearing of 4/14/89 re defendant's motion to clarify or stay injunction of 4/21/88, C.A.V., filed.
4/17/89	310	Order that deft's motion to clarify or stay injunction of 4/22/88 is denied, filed. 4/17/89 entered and copies mailed.
6/9/89	312	Defendant Medtronic's renewed motion for interim clarification or stay of injunction of 4/21/88, cert. of serv., filed.
6/16/89	315	Lilly's response to Medtronic's renewed Motion for interim clarification or stay of the injunction of 4/21/88, cert. of serv., filed.
6/19/89	316	Medtronic's reply to Lilly's response to Medtronic's renewed motion for interim clarification or stay the injunction of 4/21/88, cert. of serv., filed.
6/27/89	317	Plaintiff's response to court's proposed form of injunction, filed.
6/28/89	318	Order that Medtronic's renewed motion for interim clarification is granted in part & injunction entered 4/21/88 is modified, etc, filed. 6/28/89 entered and copies mailed.

8/7/89	321	Medtronic's Memo re: scope of new trial in light of Federal Circuit decision, filed.
8/17/89	322	Order that a hearing shall be held to determine whether deft is entitled to the defense provided in 35 U.S.C. 271(e)(1). Decision on Medtronic's post-trial motions shall be withheld until conclusion of hearing. On 9/6/89 a phone conference shall be held to discuss the scheduling of hearing, filed. 8/17/89 entered and copies mailed.
8/24/89	323	Medtronic's formal objection to and Motion for reconsideration of Order of 8/16/89, and memo, certificate of service, filed.
9/6/89	324	Lilly's memo in opposition to Medtronic's Motion for Reconsideration of the order of 8/16/89, filed.
9/19/89	325	Pre-trial conference memo—9/7/89, filed.
9/20/89	326	Medtronic's memo re scope of Fed.R.Evid. 104 Hearing and Conditional Request clarification.
10/23/89	327	Plff's motion for an Order to show cause why Medtronic should not be held in contempt for directly violating paragraphs 1 & 3 of the injunction DTD 4/21/88 as modified on 6/28/89, Memo, Cert. of Serv., filed.
10/25/89	328	Order that by 11/3/89 Medtronic will file response to Lilly's Motion for an Order to show cause why Medtronic should not be held in contempt for directly violating court's injunction orders. On 11/16/89 at 10 A.M. Hearing will be held on Lilly's contempt motion, on 10/3/89 at 2 P.M. a pretrial telephone conference will be initiated from chambers, filed.

**RELEVANT DOCKET ENTRIES
COURT OF APPEALS**

**PLAINTIFF-APPELLEE
ELI LILLY AND
COMPANY**

**DEFENDANT-APPELLANT
MEDTRONIC, INC.**

DOCKET NO. 88-1409

DATE	NR	PROCEEDINGS
5/12/88		Notice of appeal filed by the Defendant in the District Court. (1c)
6/6/88	1	Appellant's motion for stay of injunction pending appeal, filed. (SD-6/3-M).(bam) (SEE ORDER DATED 7/28/88).(bam)
6/13/88	3	Appellee's brief in opposition to appellant's motion to stay injunctive relief (also exhibits 1 thru 40, attached), filed. (SD-6/11-M).(bam) (SEE ORDER DATED 7/28/88).(bam) * <u>[CONFIDENTIAL]</u>
7/25/88		BRIEF FOR THE APPELLANT, filed. (SD-7/25-M)(cr)
7/28/88	8	IT IS ORDERED: Medtronic's motion for stay pending appeal is DENIED.(per PN).(bam)
8/31/88		SUGGESTION FOR HEARING IN BANC filed by appellant (SD-8-30-M). mym 8-31-88: SOP 18 circulated. 9-20-88: SOP 18 (response) circulated. DECLINED: 10-6-88 9/7/88 BRIEF FOR THE APPELLEE, filed. (SD-9/6-M) (jb)

9/14/88 9 Appellee's motion for leave to file a brief opposing the suggestion for hearing in banc (brief in opposition attached), filed. (SD-9-13-M). (bam) (EOD 9/16/88) GRANTED: 9/20/88. (per df on 9/19/88). (bam)

9/23/88 REPLY BRIEF FOR APPELLANT & SEPARATE JOINT APPENDIX, filed. (Separate Joint Trial Exhibits (4 copies)) (SD-9/23-M) (jb)

10/18/88 11 Appellee's motion for leave to file surreply brief instanter (reply brief attached), filed. (SD-10/17-M).(bam) DENIED: 10/28/88 (per df at direction of panel)

10/31/88 13 Appellant Medtronic's errata to reply brief citation, rec'd. (SD-10/31-H). (bam) (EOD 11/2/88)

11/3/88 ARGUED. (Nies, Archer, JJ, and Cowen, SJ) dw

11/3/88 Court has requested counsel for both sides to submit brief in 15 days, not to exceed 10 pages (due 11/18/88). (per JH) (df)

11/18/88 SUPPLEMENTAL BRIEF FOR THE APPELLANT, filed. (SD-11/18-M) (jb)

11/18/88 SUPPLEMENTAL BRIEF FOR THE APPELLEE, filed. (SD-11/17-M) (jb)

11/23/88 17 Appellee's supplemental citations relating to recent statutory amendments to 35 U.S.C. sections 156(b) and 271(e)(1), rec'd. (SD-11/23-M). (bam) (EOD 11/29/88) (Circulated to panel on 11/29/88).(bam)

3/2/89 18 Appellee's citation of supp auth, rec'd. (Cir to the panel.) (MS-3/2) (scg)

3/3/89 19 Appellant's citation of additional authority, rec'd. (FS-3/3).(bb) (Circulated to panel on 3/7/89).(bb)

3/29/89 REVERSED AND REMANDED. (Nies, J.) "JUDGMENT ENTERED" (lrp) Each party shall bear its own cost. 872 F.2d 402

4/7/89 20 Appellant - Motion to expedite issuance of the mandate. (MS-04/06/89) Filed: 04/07/89. Reply 1 (21) Filed: 04/10/89. Action on Motion (20): Denied by merits panel. Filed: 04/11/89. (EOD 04/11/89) (88) 88-1409

4/11/89 APPELLEE'S PETITION FOR REHEARING AND SUGGESTION FOR REHEARING IN BANC, filed (SD-4/11/89-M). (Id) SOP 16 circ. 4-14-89. (Id)

25 Appellant's supplemental citation of recent congressional action relating to 35 U.S.C. Sec. 271(e)(1). (Circulated to panel on 4/12/89) (MS-04/11/89) Received: 04/12/89 (EOD 04/12/89) (88) 88-1409

26 Zimmer/Bristol - Motion of Zimmer, Inc. and Bristol-Myers Co. for leave to file a brief as amici curiae in support of petition for rehearing and suggestion for rehearing in banc. (MS-04/12/89) Filed: 04/12/89. Action on motion (26): Granted by merits panel. Filed: 04/14/89. (EOD 04/14/89 by 88) 88-1409

27 Hatch/Moorhead - pro se motion of amici curiae, The Hon. Sen. Orrin G. Hatch and the Hon. Represen. Carlos J. Moorhead under Fed. R. App. P 29 for leave to file the accompanying brief amicus curiae in the above identified appeal. (MS-

04/12/89) Filed: 04/12/89. Reply 1 (20) Filed: 04/17/89. Reply 2 (29) Filed: 04/20/89. Action on motion (27): Granted by merits panel. Filed: 04/17/89. (EOD 04/21/89 by 88) 88-1409

30 Appellant - Medtronic's motion for relief under Fed. R. App. P. Rule 8(a) from injunction of April 21, 1989. (MS-04/20/89) Filed: 04/20/89. Action on motion (39): Denied by merits panel. Filed: 04/24/89. (EOD 04/24/89 by 88) 88-1409

32 Ventritex, Inc. - Motion of Ventritex, Inc. for leave to file a brief as amicus curiae in opposition to petition for rehearing and suggestion for rehearing in banc. Not served. Filed: 05/01/89. Action on motion (32): GRANTED by merits panel. Filed: 05/10/89. (EOD 05/10/89 by 88) 88-1409

33 Telectronics - Motion of Telectronics, Inc. for leave to file a brief as amicus curiae in opposition to both the petition for rehearing and suggestion for rehearing in banc. (MS-05/01/89) Filed: 05/01/89. Action on Motion (34): GRANTED by merits panel. Filed 05/4/89. (EOD 05/4/89 by 88) 88-1409

5/1/89

APPELLANT'S ANSWER TO PETITION FOR REHEARING & SUGGESTION FOR REHEARING EN BANC, filed (S.D. - 5/1/89-M). (1d) SOP 16 (response) circ. 05-02-89. (1d).

35 Procter/Gamble - Motion by the Procter & Gamble Company for leave to file a brief amicus curiae in support of petition for rehearing and suggestion for rehearing in banc after 14-day period for filing such brief. (MS-05/05/89) Filed: 05/08/89. Action on Motion (36): DENIED by merits

panel. Filed 05/25/89. (EOD 05/25/89 by 88) 88-1409

36 Pfizer Hospital - Motion by Pfizer Hospital Products Group, Inc. and Pfizer Inc. for leave to file a brief amici curiae in support of petition for rehearing and suggestion for rehearing in banc after 14-day period for filing such brief. (MS-05/23/89) Filed: 05/26/89. Action on motion (36) DENIED by merits panel. Filed 05/30/89. (EOD 05/30/89 by 88) 88-1409

5/31/89 Appellee's Petition for Rehearing DENIED: 505-31-89. (1d) SOP 18 Circ. 05-31-89. (1d).

37 Amer Sterilizer - Motion by American Sterilizer Company for leave to file a brief amicus curiae in support of petition for rehearing and suggestion for rehearing in banc out of time. (MS-05/31/89) Filed: 05/31/89. Action on motion (37). DENIED by merits panel. Filed: 07/17/89. (EOD 07/17/89 by SCG) 88-1409

38 Appellees - Lilly's motion to enlarge the time before issuance of the mandate under Fed. R. App. P. 41(A) or, in the alternative, to stay issuance of the mandate under Fed. R. App. P. 41(B). (MS-06/05/89) Filed: 06/05/89. Reply 1 (38) Filed: 06/06/89. Action on motion (38): The Motion is Denied by merits panel. Filed: 06/08/89. (EOD 06/08/89 by 88) 88-1409

6/8/89

MANDATE ISSUED TO THE ED/PA. (LC)

7/18/89

Appellee's Suggestion for Rehearing In Banc DECLINED: 07-18-89 (1d) PUB. CORRECTED ORDER DECLINING with dissent by PN. (1d)

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

Eli Lilly and Company,
Plaintiff,

v.

Medtronic, Inc.,
Defendant.

Civil Action No. 83-5393
Before the Honorable
J. William Ditter, Jr.

DECLARATION OF PETER BARTON HUTT

1. I am a partner in the Washington, D.C., law firm of Covington & Burling, specializing in food and drug law and in government regulation of health and safety. From 1971 to 1975, I was Chief Counsel for the United States Food and Drug Administration (FDA). I am co-author of *Food and Drug Law: Cases and Materials* (Foundation Press 1980), serve on the editorial board of the *Food Drug Cosmetic Law Journal* and several other journals, and have published numerous papers on food and drug law. My curriculum vitae accompanies this Declaration.

2. I have first-hand knowledge of the provisions and legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (DPC-PTR Act), which was enacted on September 24, 1984. In particular, I represented the Pharmaceutical Manufacturers Association (PMA) during the negotiations among divergent industry groups and members of Congress over the content and language of the Act. PMA is a voluntary nonprofit association of over 100 companies that are responsible for discovering, developing, manufacturing, obtaining FDA approval of, and selling almost all of the pioneer prescription new drugs in this country.

3. I make this Declaration in support of plaintiffs' memorandum supporting nonapplicability of 35 U.S.C. § 271(e)(1) to Medtronic's infringing devices. This Declaration is based on my personal recollection of the events leading to enactment of 35 U.S.C. § 271(e), the language and legislative history of the provision, and documents embodying a contemporaneous interpretation of the scope of the provision.

(a) During the approximately two years of consideration of this legislation, I was personally involved in drafting, and in meetings and telephone conversations concerning principal provisions of, the legislation. In addition, our Firm compiled a legislative history of the Act.

(b) Based on my personal knowledge, just prior to enactment I prepared a contemporaneous summary of the legislation. In late 1984 I co-authored an extensive memorandum for our pharmaceutical industry clients on the Act and its implications. On the basis of that, I co-authored an article on the Act that was published in July 1985, "Balancing Competition And Patent Protection In The Drug Industry: The Drug Price Competition And Patent Term Restoration Act of 1984," 40 Food Drug Cosmetic Law J. 269 (1985).

(c) All of these documents represent contemporaneous interpretations of the Act and, in particular, of the legislative intent underlying some of the more ambiguous statutory provisions. Such contemporaneous documentation is extremely important in resolving controversies over interpretations of the Act, because the legislative history is relatively sparse and fails to elucidate some of the Act's key provisions.

4. In addition to representing PMA during consideration of the DPC-PTR legislation, I served as counsel for PMA before the United States Court of Appeals for the Federal Circuit and the United States Supreme Court when PMA appeared as *amicus curiae* in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F. 2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984). In that case, the Federal Circuit held that the testing of a patented drug to meet FDA approval requirements, before the expiration of a valid patent, constitutes infringement. This decision was overruled by Section 202 of the DPC-PTR Act, which added Section 271(e) to Title 35 of the United States Code. This statutory provision and the underlying legislative intent are at issue in the case before this Court.

OVERVIEW OF DPC-PTR ACT PROVISIONS

5. Title I of the DPC-PTR Act established the procedures under which the FDA may approve applications for generic versions of pioneer new drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act requires every person who wishes to market a new drug to submit a new drug application (NDA) demonstrating the safety and effectiveness of the drug before the drug may be marketed. A "full NDA" contains all of the required animal and human proof of safety and effectiveness, accumulated through years of testing. A new drug for which a full NDA is submitted to FDA is called a "pioneer new drug" (or, under the DPC-PTR Act, a "listed" drug). In contrast, a new drug for which approval is sought on the basis that it is equivalent to a previously approved pioneer drug, and for which no animal and human studies on safety and effectiveness are independently conducted, is called a "generic drug." An application to market a generic drug is called an "abbreviated NDA" or "ANDA." Title I of the DPC-PTR Act authorized the submission and approval of ANDAs for an enormous number of human drug products that had not been subject to generic competition before the law was enacted.

6. Title II of the Act restores part of the patent protection lost by new drugs, antibiotic drugs, human biological products, medical devices, and food and color additives as a result of FDA premarket testing and approval requirements. Data presented to Congress have demonstrated that the 17-year patent protection had been seriously eroded for pharmaceutical products. Because of the increase in FDA research, testing, and approval requirements, a drug patent was shown to have a much shorter effective life, less than half the 17 years provided by Congress under the patent law. Title II of the 1984 legislation was designed to restore at least part of the lost patent life for FDA-regulated products.

7. Title II also added 35 U.S.C. § 271(e) to the patent law. Section 271(e)(1) provides as follows:

"(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and

Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."

The purpose of this provision was to overrule the decision in the *Bolar* case, and thus to facilitate FDA approval of generic copies of new drugs through the ANDA provisions consistent with the public policy embodied in Title I of the DPC-PTR Act. As described in detail below, it was clear to me, and I believe to virtually all persons who were involved in the consideration of the legislation, that 35 U.S.C. 271(e)(1) was intended to apply only to patented human drug products, not to any other patented invention. The legislation was intended to be extremely narrow and to overrule *Bolar* only as the case applied to patented human drug products.

THE BOLAR CASE

8. In *Roche Products, Inc. v. Bolar pharmaceutical Co.*, Bolar used Roche's patented drug, while the patent remained valid and unexpired, to begin to perform the research required to formulate its own generic drug product. Bolar also used the patented invention to begin to develop the data that must be submitted to FDA in an ANDA in order to obtain approval to market the generic drug product. Bolar asserted that it had the right to encroach upon Roche's patent, without authorization from Roche, for purposes of developing and testing its competitive drug product.

9. The Court of Appeals for the Federal Circuit held that this use by Bolar was an infringement of Roche's patent. The unlicensed use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving it of profits from the sale or licensing of the drug to other drug manufacturers, during the patent term, for whatever development and testing is necessary to satisfy regulatory requirements. The Federal Circuit decision prohibited Bolar from obtaining the benefits of such a sale or license arrangement without authorization from Roche.

10. Bolar also argued that it should be permitted to encroach upon the unexpired patent to develop its competitive product and to perform the tests required for FDA approval of the product so that it could compete with the patented product immediately upon expiration of the patent. It would have taken Bolar approximately two years to copy the pioneer drug, do the testing required, and obtain the expedited FDA approval that existed for generic products. Bolar was asking the Court of Appeals to allow it to encroach upon Roche's valid and unexpired patent for that two-year period. According to Bolar, any other result would extend for two years after patent expiration the monopoly of patent holders in the pharmaceutical industry. The Court of Appeals refused to allow this commercially significant encroachment in the guise of an expanded "experimental use" defense to liability for infringement.

11. The Federal Circuit therefore held that the unlicensed use of a patented human drug for development, testing, and other purposes in order to satisfy FDA regulatory requirements is an illegal infringement.

12. Bolar had argued to the Federal Circuit that public policy favors generic drugs and thus mandated the creation of a new exception to the patent law's prohibition on unlicensed use of a patented product that would apply only to generic drugs. The Federal Circuit declined to create such an exception, which it considered "legislative activity proper only for the Congress." 733 F.2d at 864. In fact, Congress created this special exception for generic human drug products when it reversed the *Bolar* decision through 35 U.S.C. § 271(e)(1) in conjunction with enactment of Title I of the DPC-PTR Act facilitating the approval of generic human drugs.

13. In sum, Title I of the DPC-PTR Act was intended to speed the approval of generic copies of human drug products. Title I did not apply to any other FDA-regulated products. In order to facilitate further this newly adopted public policy, Congress overruled the *Bolar* decision to the extent necessary to allow generic drug manufacturers to develop and test a drug product before expiration of a patent so that the generic manufacturer can compete with the patented drug product immediately upon expiration of the patent. Because Congress

did not enact similar expedited approval provisions for FDA-regulated products other than human drugs, it would be illogical to conclude that Congress intended to overrule *Bolar* for all FDA-regulated products, including medical devices and food additives, or to overrule *Bolar* for all patented inventions. Rather, Congress in 35 U.S.C. § 271(e)(1) was creating a narrow exemption from the patent law's use prohibition to further the specific public policy relating to human drug products that was embodied in the ANDA provisions of Title I of the DPC-PTR Act.

LANGUAGE AND LEGISLATIVE HISTORY OF 35 U.S.C. § 271(e)(1)

14. Section 271(e)(1) is quoted above in paragraph 7. The Section provides that it is not an act of infringement "to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The statutory language itself thus applies to the use of a patented invention to obtain approval under Federal laws regulating *drugs*, not any other type of product. The language omitted in the quote above explicitly states that the provision does not apply to a new animal drug or a veterinary biological product, making it clear that Section 271(e)(1) applies only to *human drugs*. Thus, by its terms, 35 U.S.C. § 271(e)(1) authorizes the use of patented human drug products, without a license, in order to develop, test, and submit a marketing application under Federal laws regulating human drugs. Such laws include the provisions of the FD&C Act that were added by the Drug Amendments of 1962 (including Section 505 of the FD&C Act, 21 U.S.C. § 355), the Biologics Act (42 U.S.C. § 262), and Section 507 of the FD&C Act governing certification of antibiotics (21 U.S.C. § 357). Such federal laws do not include, for example, the Medical Device Amendments of 1976, which added 21 U.S.C. §§ 360c-360k.

15. Further evidence that Section 271(e)(1) applies only to human drug products is found in the other paragraphs of Section 271(e). Paragraph (2) defines as an act of infringement the premature submission of an ANDA to obtain marketing approval for a generic drug before expiration of the patent on the pioneer drug. Paragraph (3) relates back to paragraph (1) in defining

the relief permitted for an act of infringement, and paragraph (4) applies to remedies for infringement of a human drug patent. The intertwining of these four paragraphs indicates that they were all intended to apply to the same type of patented product, namely patented human drug products. Therefore, when viewed in the context of the four provisions of Section 271(e), it is clear that paragraph (1), which reverses the *Bolar* decision, was intended to apply only to human drug products consistent with the other paragraphs of subsection (e).

16. The formal legislative history of the DPC-PTR Act is sparse. The legislation was introduced in the House on July 19, 1983, substantially revised and introduced in the Senate on June 12, 1984, and reported by the House Committee on Energy and Commerce on June 21, 1984 (H.R. Rep. No. 857, Pt. 1, 98th Cong., 2d Sess.). Various provisions of the bill were amended and reported by the House Committee on the Judiciary on August 1, 1984 (H.R. Rep. No. 857, Pt. 2, 98th Cong., 2d Sess.). There is no Senate report on this legislation. Consideration of the legislation and passage by the Senate and House occurred on August 10, September 6, and September 12, 1984. The statute was signed by the President on September 24, 1984.

17. The reports of both House committees indicate that 35 U.S.C. § 271(e)(1) was intended to apply only to patented human drug products, and not to all patented inventions or even all FDA-regulated patented inventions. The Report of the House Committee on Energy and Commerce (p. 45) provides:

"Section 271(e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs. This section does not permit the commercial sale of a patented drug by the party using the drug to develop such information, but it not does permit the commercial sale of research quantities of active ingredients to such party. The information which can be developed under this provision is the type which is required to obtain approval of the drug."

This description of Section 271(e)(1) focuses solely on the use and approval of drugs. This Committee Report also links the provisions of Section 271(e)(1) with the provisions of Title I. The Report (p. 46) states that Title I permits the filing of ANDAs for generic drugs and "contemplates that the effective approval date will be the expiration date of the valid patent covering the original product." Section 271(e)(1) of Title II was intended to assure that the patent term would not be indirectly extended by requiring generic drug manufacturers to spend two years following expiration of the patent to develop, test, and obtain approval of an ANDA (*id.*).

18. The Report of the House Judiciary Committee also indicates that Section 271(e)(1) applies only to human drug products. For example, in discussing the provision overruling the *Bolar* case, the Report reprints in its entirety an opinion of the Congressional Research Service of the Library of Congress, American Law Division. That Report describes the provision overruling *Bolar* as follows:

"In § 202 [of the DPC-PTR Act], Congress would provide that it is not an infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA premarketing approval of a drug." H.R. Rep. No. 98-857, Pt. 2, at 27 n.18.

This passage, which was reprinted as part of the House Report, shows that the focus of Section 271(e)(1) was to overrule *Bolar* only to the extent it related to applications for approval of drugs.

19. During a Hearing before the Senate Committee on Labor and Human Resources on June 28, 1984, Professor Norman Dorsen of New York University School of Law submitted a prepared statement in which he reviewed the provision overruling the *Bolar* case to determine if it presented any serious constitutional problems. Throughout his prepared statement, Professor Dorsen discusses the *Bolar* case and its implications solely in terms of human drug products. *Drug Price Competition and Patent Term Restoration Act of 1984*: Hearing on S.2748 Before the Senate Committee on Labor and Human Resources, 98th

Cong., 2d Sess. 179-203 (June 28, 1984). In particular, Professor Dorsen offered this description of the impact of Section 271 (e)(1) on the *Bolar* decision, which clearly indicates his conclusion that it would affect only human drug patents:

"Section 202 of the proposed legislation would reverse the *Bolar* decision in its entirety, not just for the patent involved in that case, but for all existing drug patents. Indeed, the bill would go beyond the infringing conduct involved in *Bolar* by making it lawful for an infringer to make and to sell as well as to use the patented substance during the period of the patent grant, if done for the purpose of securing FDA approval of a new drug. It would also reverse existing patent law by prohibiting courts from issuing an injunction against making, using or selling the substance for that purpose, and it would withdraw from the patentee his current right to collect damages for such infringement."

Id. at 182.

Other portions of Professor Dorsen's statement similarly suggest that Section 271(e)(1) was limited only to drug patents. *Id.* at 180, 181, 198.

CONTEMPORANEOUS INTERPRETATIONS OF 35 U.S.C. § 271(e)(1)

20. As indicated in paragraph 16 above, there is no Senate report on this legislation. The absence of a Senate report is due to the rapidity with which the legislation was ultimately considered, amended, considered again, and enacted. Nevertheless, shortly before Senate passage of the legislation, consideration was given to the issuance of a Senate report. On behalf of PMA, and based on my intensive personal involvement in the negotiations and discussions over the legislation, I prepared a contemporaneous summary of the legislation just prior to its enactment.

21. My contemporaneous summary describes Section 271(e)(1) as follows:

"Section 202 amends section 271 of the patent law to add a new subsection establishing the circumstances under which use of a patented human drug is and is not an infringement of a valid unexpired patent.

"The provision states that it shall not be an act of infringement to make, use, or sell a patented human drug product solely to obtain the information required by FDA to obtain approval of an abbreviated NDA or paper NDA. The provision is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products. If any patented invention were used in violation of the patent in conjunction with the testing of the patented human drug product, this provision would not exempt it from a determination of patent infringement. Thus, a patented calibration device could not be used under this provision in a way that violated the patent even though it was used in conjunction with the permitted testing of a generic drug.

"The intent of this provision is solely to overrule the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), which held that the testing of a patented drug to meet FDA requirements, before the expiration of a valid patent, constitutes infringement. It is therefore extremely narrow. It applies only to a patented human drug product, not to any other invention. It does not allow any patented human drug product to be commercially marketed in violation of a patent. It only allows testing. No generic drug can be sold to a single physician or a single consumer until FDA approves it. No generic drug can be tested or used for purposes other than to obtain data and information required for FDA approval, before the patent expires. The provision, in short, does not give generic manufacturers a license to do whatever they wish before a patent expires. It is intended only to permit the testing essential for FDA approval, at the expense of the generic company."

Neither this nor any other Senate report was issued due to the press of time.

22. I have also explained that Section 271(e)(1) applies only to human drug products in an article published in July 1985, which is referenced in paragraph 3 above. That article states:

"Patent Infringement. New section 271 (e)(1) states that it shall not be an act of infringement to make, use, or sell a patented human drug product solely to develop the information required by FDA to obtain approval of an ANDA or a paper NDA. This provision is limited to human drug products, and does not include medical devices, animal drugs, food additives, color additives, or other related products.

"This provision overrules the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, which held that the testing of a patented drug to meet FDA requirements before the expiration of a valid patent constitutes infringement. Because section 271(e) was intended solely to overrule this judicial decision, it is narrow in application. This statutory provision applies only to patented human drug product, not to any other invention. As explained in the House Report, the provision allows testing and experimental activity only for the purpose of developing information which is required to obtain approval of a drug. It does not allow the commercial sale of a patented drug by the person using the patented drug to develop such information." 40 Food Drug Cosmetic Law J. 308.

23. In sum, my contemporaneous understanding of Section 271(e)(1) was that (a) it applies only to human drug products, and not to medical devices or other FDA-regulated products or other patented inventions, and (b) it is narrow in scope in authorizing testing only for the purpose of developing information essential to obtain marketing approval of a generic drug, and does not permit broader commercial activities or use of the patented drug without a license.

24. Besides myself, other members of the food and drug bar and the patent bar who had been closely following enactment of the DPC-PTR Act also interpreted Section 271(e)(1) as being narrow in application.

(a) Alan D. Lourie, Vice President, Corporate Patents and Trademarks, and Associate General Counsel, SmithKline Beckman Corporation (who served as the primary drug industry patent lawyer who worked with me on the legislation and thus was also completely familiar with the development and intended meaning of the Act), published an article entitled "Patent Term Restoration: History, Summary, and Appraisal," 40 Food Drug Cosmetic Law J. 351 (1985), in which he stated:

"One more amendment to the patent laws is provided for by the DPC-PTR Act. Overruling the decision of the Court of Appeals for the Federal Circuit in the case of *Roche Products v. Bolar Pharmaceutical*, the new statute provides that it shall not be patent infringement to make, use, or sell a patented human drug product solely for uses reasonably related to the development and submission of information under a federal law regulating the sale of drugs. Thus, work done formulating and testing a patented drug during the life of the patent in order to be able to file an ANDA is not an infringement." *Id.* at 360.

Mr. Lourie's discussion of the statutory provision clearly focuses on human drug products.

(b) Steven J. Goldstein, Patent Counsel with The Procter & Gamble Company, published a paper entitled "The Drug Price Competition And Patent Term Restoration Act Of 1984 Title II — Patent Extension Provisions," 40 Food Drug Cosmetic Law J. 363, 367 (1985), in which he states:

"The DPC-PTR Act presents the anomalous situation that while the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."

Mr. Goldstein further states that the use of the patented drug

must be reasonably related to the drug approval process, and cannot extend to any and all unlicensed uses. *Id.*

25. Throughout the course of debate on the provision overruling *Bolar* no industry groups other than the drug industry became involved or participated. If any other FDA-regulated industry — such as the medical device industry — had even suspected that the provision overruling *Bolar* would adversely affect their patented products, they would certainly have made their objections known to Congress. This provision was extensively discussed in the trade press. Virtually all of the lawyers involved in the negotiations had clients in the medical device industry and food industry as well as in the pharmaceutical industry. Since all of the other FDA-regulated industry groups were silent on the *Bolar* provision, they obviously understood that 35 U.S.C. § 271 (e)(1) would overrule the *Bolar* holding on the patent law's use prohibition only as to human drug products, and not as to medical devices or other patented inventions.

CONCLUSION

26. Based on my personal knowledge of the statutory provision at issue in this case, my participation in the drafting and consideration of the legislation enacting that provision, and the documentary sources discussed in this Declaration, I conclude that 35 U.S.C. § 271(e)(1) applies only to patented human drug products and does not apply to medical devices or other FDA-regulated products. I further conclude that Section 271(e)(1), in overruling *Bolar*, provides only a narrow exemption for the unlicensed use of a patented human drug product, authorizing only the development of information essential to the approval of an application for marketing a generic human drug product.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on July 3, 1987.

/s/ PETER BARTON HUTT

PETER BARTON HUTT

Medtronic's 1st, 2nd and 3rd Responses To Plaintiff's Interrogatory No. 12

INTERROGATORY NO. 12

12. State whether any application for patent, either U.S. or foreign, has been filed by defendant Medtronic directed to either cardioverters or catheter electrodes; if so, identify each application by country, title, serial number, filing date, name of applicant, and name of inventor. For each such application, state its present status, including its patent number if a patent has issued.

OBJECTION: In addition to the general objections set forth above, Medtronic objects to Interrogatory No. 12 to the extent that it requests information about patent applications other than those which on their face are directed to cardioverters or to the catheter electrodes identified in Medtronic's objection to Interrogatory No. 9, on the ground that the interrogatory is to that extent unduly burdensome and seeks information which is not relevant to the subject matter of this action and does not appear to be reasonably calculated to lead to the discovery of admissible evidence.

ANSWER:

12. Medtronic has filed numerous patent applications on external and implantable pacemakers, pacemaker programmers and pacing leads which disclose or claim technology which is employed in the cardioverters and catheter electrodes identified in response to Interrogatories 7 and 9. Medtronic has attempted to list all such applications which on their face are directed to cardioverters or the catheter electrodes identified in answer to Interrogatory 9, but objects to the identification of other applications for patent as unduly burdensome.

<u>Medtronic No.</u>	<u>Country</u>	<u>Serial No.</u>	<u>Patent No.</u>
P-154	U.S.	125300	Abandoned
P-169	U.S.	235756	3805795
P-169 RE 1	U.S.	901962	Re. 30387
P-169 RE II	U.S.	901963	RE. 30372
P-367	U.S.	140745	Abandoned
P-367	EPO	81102888.5	Pending
P-379	U.S.	58847	Abandoned
P-379	Australia	60666/80	Pending
P-379	Canada	356555	1160296
P-379	EPO	803024132	0023134
P-379	Japan	96156/1980	Pending
P-379 Cont.	U.S.	239007	4403614
P-389	U.S.	58846	Abandoned
P-389 Cont.	U.S.	219254	4375817
P-464	U.S.	374457	Pending
P-464	EPO	83302485.4	Pending
P-499	U.S.	246528	Pending
P-504	U.S.	186368	Abandoned
P-519	U.S.	210656	4355646
P-535	U.S.	215308	Abandoned
P-542	U.S.	262863	Pending
P-542 Cont.	U.S.	499582	Pending
P-544	U.S.	241314	4384585
P-544	U.S.	82301160.6	Pending
P-661	U.S.	577635	Pending
P-674	U.S.	577631	Pending

Answer to Interrogatory No. 12

The list of applications is amended as follows:

<u>Medtronic No.</u>	<u>Country</u>	<u>Serial No.</u>	<u>Patent No.</u>
P-379	Australia	60666/80	538,816
P-464	U.S.	374,457	4,493,325
P-544	EPO	82301160.6	Pending
P-674	Canada	473,574	Pending
P-674	France	85 01 446	Pending
P-674	Germany	P 35 03 854.3	Pending

Plaintiff's Answer and Supplemental Answer to Medtronic's Interrogatory No. 7(k)

INTERROGATORY NO. 7(k)

7. Separately, for each type of automatic defibrillator identified in answer to Interrogatory 6,

(k) State the date of first sale and, by month and year, the number and dollar volume of sales of automatic defibrillators which have been sold by Plaintiffs;

ANSWER

(k) The first sale of the AID was in December 1980. Sales figures, in units and dollars, are as follows:

<u>Year</u>	<u>Units</u>	<u>Dollars</u>
1980	2	12,000
1981	57	306,000
1982	66	507,600
1983	200	1,905,020
1984 (through April)	162	1,540,556

SUPPLEMENTAL ANSWER:

<u>(k)</u>	<u>Period</u>	<u>Units</u>	<u>Dollars</u>
	4/30/84 — 7/31/84	62	\$ 703,041
	6/1/84 — 5/15/85	363	\$ 5,174,000
	5/15/85 — 12/31/85	381	\$ 4.4 million
	1/1/86 — 12/31/86	895	\$ 10.8 million
	1/1/87 — 10/31/87	1825	\$ 23.6 million

DAY 3 TRIAL TESTIMONY OF RICHARD W. STRAIN [Strain — page 30]

'83 device is out, with the '87 timetable, so all these are projections before 1987. They are extremely relevant.

THE COURT: Well, I will sustain the objection insofar as it goes to — if what your plan was to do was to project this

page as a transparency, I will sustain the objection.

However, I will permit you to say what the sales were in '85 and '86 and then you can say that back in '80, whenever they made 24, what did you project for '87.

MR. MALLOY: Good. I will do that.

THE COURT: And I think that the figure for '87 is close enough that that would have some probative value. So I will permit you to do it that way but I will sustain the objection so far as a projection of page 12 of this exhibit is concerned

(Whereupon, the discussion concluded at sidebar.)

BY MR. MALLOY:

Q Can you tell us what Exhibit 205 is?

A Yes, sir. Exhibit 205 was a document prepared in the middle of July, 1984, by CPI in looking at the various issues and potential opportunities of integrating the implantable defibrillator into Cardiac Pacemakers, Incorporated.

Q Now, I would like you to turn to page 12, if you would.

A Yes, sir.

Q And the graph at the bottom of page 12, is that a projection made as of a particular date?

[Strain — page 31]

A Yes, sir. The large craft.

Q Excuse me. Just before you go on. Let's take it just one step at a time. This was a projection of units; is that correct?

A Yes, sir.

Q And units of what type?

A Units of the implantable defibrillator.

Q And was it a projection made as of approximately what date?

A Approximately the middle of July, 1984.

Q How many units did you project to be sold in the year 1987?

A Our projections were approximately 2,500 units.

Q Of what?

A Of the automatic implantable defibrillator.

Q And in terms of market statistics and accuracy, how did reality match up with your projection of 2,500 units in the year 1987?

A Last year we sold 23001 units.

Q And so how would you characterize that in terms of your marketing understanding and accuracy of projections?

A Well, having been in market research for almost 20 years.

MR. HEIST: Objection, Your Honor.

THE WITNESS: I felt pretty comfortable with those estimates.

BY MR. MALLOY:

Q Now, referring to the acquisition of the implantable

[Strain — page 47]

Q Now, we have heard mention of a population of patients who suffer cardiac arrest of 400,000. Are these devices sold to all those 400,000?

A Yeah. Let me discuss that [Strain - page 48] as it relates to the automatic implantable cardioverter defibrillator. In the United States annually, about 400,000 patients suffer from sudden death syndrome and it is called sudden death syndrome because you can't look at me and I can't look at you and determine that you are a candidate. So the typical patient tends to collapse. They collapse either at home, maybe in a hospital, or on the street. So of those 400,000 patients who suffer this sudden loss of consciousness, approximately 20 percent survive. So out of the 400,000, 320,000 die. 80,000 survive.

Of the 80,000 that survive, about three quarters of them can be managed with drugs, or at least it seems so today with current drugs available. So out of the 80,000 patients who have survived

one sudden death syndrome attack, 60,000 treated with drugs, 20,000 are potential candidates for this device because they cannot be managed with drugs. And these are then what we view as the potential candidates for this device, those 20,000 patients.

[Strain — page 52]

recover that right now because I don't think, 532 —

THE COURT: 532?

MR. VOGLER: We haven't referred to that one, have we?

MR. MALLOY: We are about to.

MR. VOGLER: We are about to get to it.

(Whereupon, the discussion concluded at side bar.)

BY MR. MALLOY:

Q Would you refer to Exhibit 532, please.

A Yes, sir.

Q What is Exhibit 532?

A 532 is our latest price list for the cardioverter defibrillator product line specifically.

Q And the product is called what?

A The VENTAK AIC-D.

Q What is the price of that product?

A The price of the device — the price for the PG is \$13,000.

Q PG meaning what?

A Meaning the pulse generator, but the large size of the device. And with its complete lead system would add another 3,000, so the price is somewhere between 15,000 and \$16,000 per device with appropriate leads.

Q In terms of the effect of this device, the AIC-D, automatic implantable cardioverter defibrillator that CPI was able to sell,

what effect financially and specifically did that have on CPI in the last year or two?

[Strain — page 60]

THE COURT: I didn't understand your objection.

MR. MALLOY: My objection is is he asking the witness about what Medtronic has done and not done and I object because Medtronic has withheld as confidential its business information from this witness. I think it is an improper question.

MR. HEIST: Excuse me

(Brief pause.)

MR. HEIST: Your Honor, I am advised that we have not withheld as confidential the number of implants that have been accused.

MR. MALLOY: They withheld all the business information from Medtronic.

THE COURT: Well, I don't know what has been disclosed or what was withheld from this witness or otherwise. If you want to pursue it, I will see you at sidebar. Or why don't you talk about it with each other and see if you can agree upon what you are talking about, because I don't have any information one way or the other.

(Brief pause.)

BY MR. HEIST:

Q Are you aware that Medtronic's devices, accused devices, have not yet received final FDA approval?

A I am aware that no other devices other than ours have received FDA approval.

Q Now, Lilly's commercial product, its defibrillator product, [Strain — page 74] on the upswing and I guess the answer is yes or no.

MR. MALLOY: Well, yes or no with an explanation, Your Honor, which I think would be appropriate.

THE COURT: Well, I think we all know what the answer

will be and so you can ask him when it comes your turn.

MR. MALLOY: Okay.

BY MR. HEIST:

Q Now, I understood you to say that there were 400,000 patients a year who are susceptible to sudden death and that of those, approximately 80,000 — pardon me, approximately 20,000 are candidates for defibrillators?

A Yes, sir, potential candidates.

Q And if I understood your sales figures for 1987, I believe it was, you sold around 2300 defibrillators?

A That is correct.

Q So that's a little bit more than 10 percent of the market?

A Yes, sir, that's true.

Q Now, if you will assume with me that Medtronic has implanted 20 units since 1983, that's about four or five units a year, since that time.

THE COURT: Well, on the average.

BY MR. HEIST:

Q On the average. Do you know what percentage of the market that constitutes?

A No, sir, I don't.

[Strain - page 76]

Q The figure 2300 units which was the figure for 1987, that was the filling of every order CPI received; correct?

A Yes, sir. That is right.

Q Now, 2300 is still less than the 20,000 figure of potential candidates. Why the difference between those two numbers?

A Well, I have used in our forecast and for forecast purposes with a product as invasive as this is — and I guess maybe a little background is necessary here. The FDA approval for this

device basically made it a therapy of last resort. It meant that if a patient could not take drugs and control their problem, then the next step was go through surgical applications, which was a surgical procedure which I will not explain because I don't really have the talent to. And then if that was not successful, then, and only then, would the patient be a candidate for the automatic implantable defibrillator.

It was our very strong feeling that this is very [Strain — page 77] fragile therapy, it is very early in its life, it is very early in its acceptance, and so the fragility of that means that having devices in the marketplace that work, educating the physicians and, as you notice, I had concentrated earlier on talking about the electrophysiologist as the key, a very technical specialist in implanting these devices, well key to him getting patients who are candidates for these devices is also our work with what we call invasive cardiologists that would bring in potential customers to the electrophysiologist for this kind of therapy.

So I think it is safe to say that the therapy is on the leading edge. It is not accepted by all physicians. You can see from the clinical data I shared with you that it is definitely lifesaving, but the specification for the appropriate patient is something that still is emerging. So when I felt, given the product as it is today, there is a potential for 20,000 patients a year to be treated, I still feel very strongly about that. Getting there will take more time and more education on the part of ourselves and on the part of physicians.

DAY 3 TRIAL TESTIMONY OF
MICHAEL M. TOFFOLI
[Page 150]

Q I would like to draw your attention to the third page of Exhibit 139."

MR. MALLOY: Could we have the third page.

"Q And ask you what you are trying to depict by the graph on this page?

A This page basically takes the market projection from the first

page and adds to that projection our, Medtronic's unit plan for PCD's, my expectation of what Intermedics would be [Toffoli - page 151] able to do in the market with their version of a pacemaker, cardioverter defibrillator, and also recognizes that during the early 90's we should expect to see other manufacturers attempting to introduce products and that in all likelihood they will eke out some small volume.

Q Does the graph depicted on the third page of Exhibit 139 show predicted market shares for the companies that you have listed?

A Essentially it does.

Q And that includes predicted market share for CPI?

A That's correct.

Q Did you develop any projected profits for Medtronic for fiscal years '88 through '92 for the PCD units?

A No, I have not done that.

Q Has anyone done that at Medtronic?

A I don't know. I haven't reviewed any documents that looked at — at the — you know, that looked specifically at profit projections over time.

Q Have you heard of any projected profits for Medtronic for any time for the fiscal years '88 through '92?

A I'm not aware of any specific projections.

Q Referring back to the third page of Exhibit 139, what did you use as background information to establish the market share for, market share comparisons for Medtronic, CPI and Intermedics?

[Toffoli - page 152]

A My primary considerations were based on my understanding of product evolution and product introduction likely to occur from each of those three companies over this period of time, coupled with the historical muscle that each of the three companies had demonstrated in terms of sales and marketing of their products.

Q Anything else?

A Those are the two prime ingredients in the projection.

Q Is it fair to say that Medtronic has greater historical muscle than CPI in marketing its products?

A In marketing its pacing products, I think that's definitely true.

Q Is it fair to say that Intermedics has historical — is it fair to say that Intermedics has greater historical muscle in marketing its products than CPI?

A I think that's also true.

Q Is it fair to say that Medtronic has greater historical muscle to market its products compared to Intermedics?

A I believe that's true.

Q What do you mean by the term historical muscle?

A Given somewhat equivalent product lines, what level of a share historically has each company been able to achieve. And if the product lines are essentially equivalent, then the difference in share reflects marketing and sales in service level prowess, coverage, whatever you want to call it.

Q Anything else?

[Toffoli — page 153]

A No.

Q From this graph can you tell me what market share you have estimated for Medtronic in 1/92 — and I presume 1/92 refers to fiscal year '92; is that correct?

A I believe on this chart I was looking at the year beginning in January 1992.

Q Okay. And is that the same for the chart on the first page?

A Yes.

Q On the bottom — referring again to the third page of Exhibit 139, can you give me an estimate of what you projected for the market share of Medtronic for implantable defibrillators starting the year 1/92?

A It would be easy enough to calculate it from the numbers

on the previous pages, but I believe it was somewhere in the area of 40 percent.

Q Do you remember what percentage of market share you predicted that Medtronic would have for implantable defibrillators in calendar year January '94?

A I believe in that year I was assuming we would achieve something around 45 percent. [Toffoli — page 155]

“Q Again referring to the third page of Exhibit 139 under Assumptions, there is a caption Medtronic and under that the language, “achieves current plan, including International release of 7216 summer 1989. U.S. release early 1990 with a transvenous lead during 1990.” What is meant by that entry?

A I think it is fairly straightforward. That is a statement of the assumptions underlying that projection.

Q Does that mean U.S. market release of a PCD unit with a transvenous lead in 1990 or during 1990?

A It means what it says, which in U.S. release of a PCD in early '90 with a transvenous lead during '90. That does not say early '90. There were no and there are no firm plans for that lead, so I did not assume it would be there with the PCD, [Toffoli — page 156] but that it would follow.

Q The U.S. release in early 1990 refers to the 7216 PCD?

A That's correct.

Q And was it your assumption that that would be used with a transvenous lead during 1990?

A Sometime during 1990.

[Toffoli — page 159]

MR. MALLOY: Can we put 142 on the projection?

“A Yes. This is a document that I prepared to communicate to the Medtronic Attendees at the World Pacing Symposium held in Jerusalem in June of this year what our position was regarding tachycardia management products at that medical meeting.

Q What did you intend attend [sic] the Medtronic Jerusalem attendees to do with this document?

A I intended them to read the document and be aware of its contents.

Q Is this document the position of Medtronic to be passed along to Attendees of the Jerusalem conference?”

MR. LEVIN: Objection, Your Honor. This testimony has never been designated.

MR. MALLOY: You designated it. I would be delighted to skip it. In fact, I was going to ask the Judge if I could.

THE COURT: Well, why don't you talk with each other and decide?

MR. MALLOY: I will skip right over it. I am going [Toffoli — page 160] over to line 16 on page 215. The answer at line 16.

“A The document was an internal Medtronic document and only went to Medtronic people.

Q Under item A first A on that first page there is a statement: ‘Medtronic will be the major supplier of implantable defibrillators and external EP stimulators . . . Doctor, your medium/long range partner in tachy control devices is Medtronic.’

What was your intent when you wrote that statement?

A The intent was to communicate to my colleagues that we are, indeed, committed to being a major participant in serving the needs of the electrophysiologists.”

MR. MALLOY: I would like to skip the next two pages, also. You designated them. Do you mind if I skip them?

“Q Under the heading Strategy item A states: ‘Expedite the PCD development and clinical evaluation achieving a releasable International 30 joule system by summer 1989;’ and I ask you, what were the reasons that you had in mind when you used the word ‘expedite’?

A Do everything within our control and resource capability to achieve that system.

Q Why was that?

A Because I think there is a real opportunity there.

Q What type of opportunity?

A The opportunity depicted in the revenue projection that we [Toffoli — page 161] discussed yesterday.

Q And what would be the consequences if you did not expedite that development?

A Revenue projection would be less.

Q That would be the revenue projection for Medtronic?

A Correct.

Q Referring now to item C under 'Strategy,' you state 'short term, leverage education programs and research projects that will build credibility and rep relationships critical to the future success;' and I ask: What is meant by 'leverage education programs and research projects'?

A To utilize educational offerings to the electrophysiologists, and research — joint research efforts with the electrophysiologist, to build contacts, and to determine that we are knowledgeable, credible partner in their tachycardia management efforts.

**DAY 3 TRIAL TESTIMONY OF
JOHN D. ROBERTS
[page 177]**

Q To page 35. "How did you come about your conclusion that you saw a need for the model 7220?"

A Feedback from physicians.

Q What feedback was that?

A The concern that there was no back-up defibrillation.

Q Was there a concern that there was no defibrillation back-up prior to the 7210 going into IDE Study?

A Yes.

Q Have you ever heard any reasons why Medtronic continued forward with the 7210 study despite that concern?

Q Yes.

Q What were those?

A Information would be gathered on the requirements for building a unit that could produce relatively high energy output pulses. In addition, information on detection algorithms for ventricular tachycardia.

Q Do you know if there was ever an intent to market the model 7210?

A To my understanding, there was never an intent to market the 7210.

Q Could you please refer your attention to the third paragraph of Exhibit 153, the second sentence in that paragraph which reads: 'the funds generated by implants of such a product, whether clinical, assuming the precedent set for the first model 7210 is maintained or marketed could be applied to [Roberts — page 178] additional enhancements and future devices.'

Do you see that?

A Yes.

Q Does that refresh your recollection in any way, whether there was ever an intent to market the model 7210?

A Yes.

Q What is your current recollection?

A My current recollection is that even though the word in here indicates that there was some possibility of that, I don't recall anyone ever relating to me that the model 7210 would be marketed.

Q Did Medtronic charge for the model 7210 devices?

A Yes."

Q To page 50. "What was that awareness?"

A On page 50?

Q Line three.

"A. That development of that device was ongoing.

Q Anything else?

A That there was an intent to evaluate it clinically.

Q Anything else?

A Depending upon the outcome of the clinical evaluation, it may or may not be an intent to market the product. That was about it.

Q. When you referred to the outcome of the clinical, were you referring to an IDE study?

**DAY 4 TRIAL TESTIMONY OF
JOHN D. ROBERTS
[page 88]**

"Q Have you ever heard if AICD units would be back-ups for 7215 PCD's?

A Oh, yes.

Q In what circumstances did you hear that?

A I was one of the proponents of that idea.

Q Why was that?

A Well, we were uncertain as to the number of patients that would be able to receive the Model 7215 because of a limited output capability; and since it required an open chest procedure, rather than leave the patient with nothing after opening the chest, it seemed unethical to not provide a back-up unit, and the only back-up unit that could be provided was the AICD.

**DAY 4 TRIAL TESTIMONY OF
DR. RICHARD LUCERI
[page 101]**

Q Did there come a point in time in your career when you heard of Mr. Mirowski?

A Yes.

Q Would you describe that circumstance?

A That was in approximately 1980 when a publication appeared in the New England Journal of Medicine that was authored by Dr. Mirowski and his colleagues presenting their results with

the automatic defibrillator, the first results, I believe, in humans.

[Luceri - page 102]

Q What was your reaction to that publication?

A Well, I was actually quite excited and after reading the article, I thought this was a revolutionary step in the treatment of this disease.

Q Why was that?

A Why was that?

Q Why did you think it was revolutionary?

A Because no one approached the problem in this way before and I think that after reviewing the other data available, for instance, regarding drug therapy or operations, this was the only type of approach that really stopped this problem from happening once it started.

The other methods sought to prevent the occurrence of the problem, in other words, prevent those arrhythmias from starting in the first place, but this was the only concept, to my knowledge, that stopped the arrhythmia from occurring once it started, and that in itself was revolutionary.

Q Were you aware of any criticism of Dr. Mirowski in his invention?

A Yes, I was.

Q And what was that?

A There were numerous criticisms, probably because of the — what I call revolutionary nature of the treatment. It is not unusual in this field, and I guess in all other fields, for something so radical to be ridiculed and I think Dr. Mirowski [Luceri — page 103] underwent a significant amount of ridicule that even appeared in the printed medical literature, which was quite unusual.

Q Did you undertake, after learning of Dr. Mirowski's invention, to contact him or to do anything further with respect to the device?

A Yes, I did.

Q What was that?

A In 1983 I first met Dr. Mirowski. We were at an international meeting in Vienna and the meeting was on pacing and arrhythmia therapy and Dr. Mirowski did not know me, but I obviously knew of him and I approached him and basically established contact with him and asked if I could be an investigator with this device. [Luceri — page 106] detected by these two button electrodes. They sense all of this electrical activity. And these button electrodes will send the command to the unit to tell it when it should or should not deliver a shock.

There is a secondary sensing component here that's done across the two patches, and that's called PDF. It is a complicated physical principle, but basically the sensing leads here tell the defibrillator what is going on with the heart and they continuously monitor the heart's activity and send the message to the defibrillator when to deliver the shock.

Q And how is the shock delivered? Across what and what happens when the shock comes?

A Okay. When the message comes from these two leads here to the defibrillator and all the systems are go and the defibrillator is to deliver a shock, it will charge its capacitors inside here. This is similar to a flash on a camera being charged. The batteries are there, but they don't hold the charge all the time. You have to actually press the button and have the flash charge.

When that charge is peaked, then it delivers a shock across these two patches. The shock spreads across the internal screen on the patches and, therefore, the energy goes across the two patches here.

Q And what happens to the heart when the shock is delivered?

A The heart is suddenly what we call depolarized and that's

[Luceri — page 139]

Q Prior to the time you became involved with CPI when it commenced manufacture of the automatic implantable cardioverter defibrillator, you were practicing in Florida; correct?

A Correct.

Q Had you much, if any, experience with CPI as a company before that time?

A No. I had virtually no contact with CPI prior to that time.

Q And so the automatic implantable cardioverter defibrillator was really CPI's introduction to you?

A For the most part, yes.

Q And did you then come to become more familiar with CPI as a company?

A Yes, that's correct.

Q Did the introduction of the automatic implantable cardioverter defibrillator to you have any affect in terms of your dealings with CPI?

A I'm not sure I understand what you mean by "dealings."

Q Probably I didn't phrase it very well.

Did you, after becoming involved with CPI's automatic [Luceri - page 140] implant cardioverter defibrillator also learn about CPI as a company and its other products?

A Yes, that's correct.

Q And had CPI had much of a presence in terms of its ability to market product down in your part of the country before this product came around?

A Not to my knowledge, no.

Q And what effect, from your point of view in that area of the country, did the automatic implantable defibrillator have in terms of CPI's ability to market its other products?

A I think from a marketing point of view, it gave them an introduction into that part of the country.

[Luceri — page 141]

every instance where someone has a ventricular tachycardia, they die as a result of that episode?

A No, not in every instance.

Q Are there different types of ventricular tachycardia?

A Yes.

Q Are some lower rate* that is, the heart is not going as fast as other types?

A That's correct.

Q Are there some types of ventricular tachycardia that are more stable than others?

A Yes.

Q That is, that are less life threatening?

A That's correct, yes.

Q Do they tend to be lower rate tachycardias?

A Slower, yes, they are slower.

Q They are slower?

A Mm-hmm.

Q And could you give me an example of the slow rate tachycardia?

A An example would be let's say approximately 110, 110 beats per minute, usually, depending upon the status of the heart itself. That rate can't be tolerated until the patient gets to medical attention. Of course, as I said, it all depends on the status of the heart. If the heart is very weak to start with, then even at rates as low as 110 beats per minute, which is [Luceri — page 142] within an otherwise normal exercise rate, that heart will tolerate very poorly. So if we have a more — a healthier heart, that can tolerate faster rates.

Q So for hearts that are beating 110 to 120 beats per minute, it could either be an abnormal fast heartbeat or it could be the result of normal exercise; is that right?

A Not ventricular tachycardia.

Q But just in terms of heart rate?

A In terms of rate, yes, that's correct.

Q Now, does the Intec or CPI defibrillator treat tachycardias or fast heart rates in the 110 to 120 beat range?

A No, generally not. No.

Q Are drugs sometimes given to patients who use the CPI defibrillator in order to speed up the rates of tachycardias?

A Ventricular tachycardias?

Q Yes.

A No, not to my knowledge.

Q Not to improve the sensing?

A No.

Q Now, I would like to make it clear exactly which leads were functioning that you referred to in connection with these charts. I will direct you to Exhibit 632E and direct you in particular to the lead which goes down into the right ventricle. Do you see that?

A Yes.

[Luceri — page 156]

mandatory in the protocol. They were up to the investigators

Q And the FDA knew that and was part of the protocol that had options in it?

A Yes.

Q And do you know whether there is an option in the Medtronic protocol as to whether or not to use a third patch?

A I believe there is, but -

Q You don't know.

A I don't know for sure, no.

Q Now, you testified about the quality of life of people who receive Lilly defibrillators and I'd like to direct your attention to a study that you did on the quality of life. Do you recall that study?

A Yes, I do.

Q And in that study you looked into the effects of patients who had received these defibrillators and how they - how their quality of life was after they had gotten them; is that right?

A That's correct.

Q And in that study didn't you find that about 85 percent of the patients who had gotten shocked by the defibrillator described later to you that they had what I think you called significant fear?

A Yes. They were afraid, yes.

Q And wasn't the fear of shocks one of the factors that you associated with reduced physical activity in about 65 percent [Luceri - page 157] of the people who had gotten these defibrillators?

A Yes.

Q And did you find that there was a reduction in the social interactions of these defibrillator recipients, at least in about 41 percent of the time?

A Yes, there were.

Q Did you find that sexual abstinence was reported by about 41 percent of this group?

A Yes. I believe that's the figure.

Q And did this lead you to conclude that the automatic implantable defibrillator is associated with multiple physical, social and psychological alterations?

A Yes.

Q Now, you have also reported on a technical side, I think, between interactions between the defibrillator and pacemakers in those devices where both of them are used?

A That's correct.

Q Maybe I should start, to be sure we understand each other, there is no pacemaking function that's in the defibrillator itself, is there?

A Correct.

Q So for the patients who need a pacemaker, they have to get a separate one in addition to the defibrillator?

A That's right.

Q Is that done - that's a separate expense, I assume?

[Luceri - page 158]

A Yes.

Q Is it a separate operation?

A Yes. It is two different areas of the body.

Q Now, are there sometimes interactions between the defibrillator and the pacemaker?

A Yes, there may be.

Q And is it possible in your experience that the defibrillator can ignore a fast heartbeat because it was actually listening to the pacer instead of the heart?

A Yes. That's correct.

Q And in that circumstance, it could fail to deliver a shock because it thought everything was all right?

A Yes.

Q And in your experience, it is possible that there could be what's known as double counting and which I understand - correct me if I am wrong - means that the defibrillator has to listen to both the heart and to the pacer, so that it counted more beats than actually occurred?

A Yes. That's stretching it a little bit, but there is —

Q I am trying to phrase it so the jury will be able to understand.

A Yes. That's correct. There may be double counting.

Q And when there is double counting, can that lead to unnecessary shocks to the patient?

A Yes.

[Luceri — page 159]

Q Because the defibrillator thinks that the heart is fibrillating and it really isn't?

A Correct.

Q Is this more of a problem when you use dual-chambered pacing?

A Yes, it is.

Q Even when the dual-chambered pacing is at relatively low rates?

A It may be. We've gotten around that by using bipolar dual-chamber pacemakers.

Q And that helps somewhat?

A That helps a lot.

Q Now, in addition to these problems, are there various complications and device failures which are known to occur with the Lilly defibrillators?

A Absolutely.

Q And do they include post operative heart failure, coronary artery erosion, subclavian thrombosis, postoperative stroke, pneumonia, pleural effusions and infections of the generator site.

[Luceri — page 166]

defibrillator can't be used with these tachycardias in the 110 to 120 beat range?

A It could if it had programmable rate. In other words, you can have a CPI defibrillator custom made so that the rate cutoff is below the rate you desire, such as 110 or 120. That's not the problem. The essential point here is the programmability.

You have a choice — you don't have a choice, you have one rate that comes with that particular defibrillator and since the usual rate is over 155 and most defibrillators are made — are manufactured with that as the cutoff rate.

Q And if you had one that was made to detect 110 beats, what would happen if you went out jogging?

A You may trigger inappropriate shocks if the heart rate while jogging was more than 110 beats, unless there was a more sophisticated sensing circuit.

Q Is 110 a heart rate that someone in my poor condition could raise if I went out jogging?

A Sure.

Q Now, the CPI defibrillator doesn't have any way to give sequences of pacing pulses, does it?

A That's correct.

Q So it doesn't have any way of trying to slow down the pacing of a fast heartbeat?

A That's correct.

[Luceri — page 167]

Q And it can't deliver, for example, a burst of pacing pulses, can it?

A No, it cannot.

Q And it therefore doesn't use its defibrillation energy just as a back-up for some other therapy, does it?

A No.

Q Now, isn't it true that all of these features we have just discussed you have said should be in, and I will quote you, the ideal implantable device?

A Absolutely.

MR. JOHNSON: Thank you. I have no more questions.

REDIRECT EXAMINATION

BY MR. MALLOY:

Q Doctor, does the CPI automatic implantable cardioverter defibrillator continuously or continually monitor the functions of the heart?

A Yes, it does.

Q Is that your view even though — let me ask you this:

Are there periods of time in the device when it doesn't sense, does not sense during the charging of the output capacity?

A Yes. Technically speaking, there are brief periods of time where the device does not sense. You mentioned one, when it is charging the capacitors. Another is the, what we call blanking period that occurs around the time of sensing of the QRS or

DAY 7 TRIAL TESTIMONY OF DR. ROBERT HAUSER [page 20]

BY MR. MALLOY:

Q What effect, if any, has the VENTAK automatic implantable cardioverter defibrillator had on CPI as a company?

A It has had an enormous effect. Prior to the acquisition of the AICD technology, CPI was a dying company. Its products were not on the leading edge. It was difficult for physicians to even be accessed by CPI to demonstrate the products.

With the AICD, we have attracted additional talent, engineers, clinicians, managers, technicians, nurses, everyone now is very excited about this technology and it has literally turned the company around.

We not have ready access to physicians, electrophysiologists, cardiovascular surgeons. I think it is best described by one of our long-term employees who has been with CPI since the mid 1970's. He told me that prior to the AICD, it was difficult to get physicians to answer his calls. Now he has greater access to those physicians. So it has substantially helped CPI as a company.

Q Tell us what an electrophysiologist is.

A An electrophysiologist is usually a cardiologist, but may be a cardiovascular surgeon who specializes in abnormal rhythms of the heart.

Q Has CPI done anything to help the nation's — United States' electrophysiologists in terms of treatment of [Hauser — page 21] ventricular tachycardia and ventricular fibrillation?

A Well, I think our principal contribution has been in the training of these physicians in the AICD technology. We have trained over 200 centers in the United States who are now implanting the AICD and this includes physicians and surgeons from these centers who attend a two-day course in St. Paul at CPI headquarters. This course is conducted by a faculty which includes physicians, guest speakers from Johns Hopkins, for example, or Stanford, and also the faculty includes engineers and technicians from CPI.

Q Tell us in your view what the relative significance or lack of significance of Dr. Mirowski and his invention of the automatic implantable cardioverter defibrillator is.

A Well, if you simply reflect on the facts, the fact is that we are treating a group of patients who are going to die in a fairly short period of time. With the AICD, the clinical data, the clinical information, the clinical results already show that these patients have a 95 to 98 percent chance of survival.

If you then project that onto the number of patients at risk in this country, one might anticipate that over the next 10 years the AICD will save over a half million lives, and that's equivalent to the population of Minneapolis, St. Paul. That falls into a class

of treatment, a quality of treatment, that compares favorably with insulin, with penicillin, and with cardiac pacemaker?

[Hauser — page 22]

I believe that 10 or 15 years from now medical students will be reading about Dr. Mirowski's contribution. I believe that 10 or 15 years from now, I will be telling my grandchildren or —

MR. JOHNSON: Objection. Irrelevant.

THE COURT: No. Overruled.

THE WITNESS: I believe I will be proud of what we are doing with the AICD.

I also believe that some day Dr. Mirowski will receive the Noble [sic] Prize of medicine.

MR. MALLOY: No further questions.

[Hauser — page 42]

Q Pacemakers are intended to treat either no heartbeat or slow heartbeat; is that right?

A The majority of pacemakers are used to treat no heartbeat or a slow heartbeat. There are pacemakers that are used to treat rapid heartbeats.

Q When a pacemaker is used to treat slow heartbeat or no heartbeat, that's called a bradycardia therapy?

A That's correct.

Q And it is well known, isn't it, that after you defibrillate the human heart, that bradycardia often is the result, at least for a period of time?

A That's not true.

Q You haven't experienced a lowered heartbeat after a defibrillation with your patients?

A In some patients that can occur, but it has been the report of groups such as Dr. Aker's group in Milwaukee that slow heartbeats are infrequently observed after defibrillation.

Q Now, normally when you defibrillate a heart, it starts beating again by itself, doesn't it?

A Yes.

Q Now, occasionally it doesn't start beating again by itself; isn't that right?

A Occasionally.

Q And is that called asystolen?

A Or bradycardia.

[Hauser — page 43]

Q Or bradycardia?

A Yes.

Q And if a pacemaker happens to be implanted in that patient or in the case where the device could function as one, the provision of that small stimulus would get the heart going again, wouldn't it, in most instances?

A In many cases, yes.

Q This had led you to suggest that it would be a good idea to add pacing to an implantable defibrillator, hasn't it?

A I don't know what you are referring to.

Q Have you ever suggested it would be a good idea to add pacing to an implantable defibrillator?

A Yes.

Q Dr. Mirowski and the people he has been working with have been saying that pacing would be available in the Intec CPI defibrillator shortly for quite awhile now, haven't they?

A I don't know that.

Q Do you recall attending a symposium where you were the reporter in 1984 where Dr. Mirowski spoke on that topic?

A I have attended many, many meetings, as you know from my curriculum, and perhaps you could refresh my memory.

Q Do you recall going to a symposium which you later reported the panel from entitled The Role of Devices in the Control of tachyarrhythmias?

A Was that published in Pace?

[Hauser — page 44]

Q Yes.

A Would you mind showing me the document?

MR. MALLOY: I think that would help us, Mr. Johnson.

MR. JOHNSON: I will be happy to show the doctor the document.

THE WITNESS: Yes. This was the report of a panel meeting at the National Institute of Health where I was the reporter for the NIH.

BY MR. JOHNSON:

Q You prepared this document then?

A Yes.

Q And did you report that Dr. Mirowski said that within a few months, we will have pacing capabilities as well? That's the underlined portion there?

A Yes.

Q And that was back in 1984?

A Yes.

Q And you don't have pacing capabilities yet with any commercially approved device, do you?

A No.

Q Are there patients with tachyarrhythmias now who are not good candidates for the CPI defibrillator?

A Patients with atrial tachyarrhythmias are not candidates for the device. Patients who do not have critical rapid heartbeats are not candidates for the device.

DAY 16 TRIAL TESTIMONY
OF DR. ROBERT HAUSER

[page 35]

BY MR. MALLOY:

Q Doctor, in your direct testimony during our case in chief you testified a little bit about therapy acceptance. I want to ask you a couple questions abouts CPI's present plans for training as they relate to therapy acceptance, and simply as a background so that we have a context, would you tell me what you mean by therapy acceptance with respect to the automatic implantable cardioverter defibrillator.

A Yes. Therapy acceptance is a phrase that we have used and others have used to describe the understanding and application of any treatment which may include a drug, surgery or device, and typically, as a new therapy is introduced, and the information is disseminated in the medical community, there is some acceptance curve that one can describe based on the utilization of that therapy. One can accelerate acceptance by improving the dissemination of information to the medical community.

Q Is there any question of the strength or fragility of therapy acceptance as it relates specifically to the automatic implantable cardioverter defibrillator?

A I think with any new therapy it is important to introduce it in a very systematic fashion based on solid scientific evidence.

Q Is it possible in your view that a device in this very same

[Hauser — page 36]

field introduced but with defects and which doesn't work properly could have an effect on that therapy acceptance?

A Unquestionably.

Q Now, what, if anything, is CPI doing in terms of its present plans to train cardiologists or electrophysiologists if that has any bearing at all on therapy acceptance?

A Well, we simply want to insure that the device is properly applied, we are doing so, as I mentioned during my original

testimony, by conducting seminars at CPI, which include some experience in the pre-clinical laboratory. Next week, for example, at the American College of Cardiology, we will have a symposium and AICD therapy, which will include cardiologists, electrophysiologists and other physicians potentially.

This year we plan to conduct additional programs for positions all around the world. They will either be at CPI or at Satellite Symposia. We actually plan over 100 such meetings during 1988.

Q And the meetings are to train whom with what?

A They are intended to familiarize physicians who may not implant the device with the benefits and the proper indications for the device. They are intended to train physicians specifically as some programs are designed to acquaint physicians with the technical characteristics of the device, the implantations techniques and the follow-up care of these patients.

**DAY 7 TRIAL TESTIMONY OF
MICHAEL KALLOK
[page 78]**

"BY MR. MALLOY:

Q Has it ever been suggested by anyone to your knowledge at Medtronic that the first unit of the 7215 should not be implanted in the United States?

A Yes, I believe that's been suggested.

Q By whom?

A I don't know that I remember the individual.

Q What reasons, if any, were given for the expression that the first unit of Model 7215 should not be implanted in the United States?

A The reason I am aware of is that it was possible to implant a unit in Canada prior to approval by the FDA to implant a unit in the United States.

Q To date where have all units of the Model 7215 been manufactured?

A At Medtronic's facility in Fridley —

Q Minnesota?

A — to the best of my knowledge. Yes. The final assembly of those units did not occur at Medtronic's facility in Fridley, Minnesota.

Q Why not?

A The final assembly occurred at Medtronic's facility in Canada.

Q Why?

A The FDA does not permit a device that is not approved for

[Kallok — page 79]

clinical trials to be exported from the U.S. However, subassemblies of those devices can be exported from the U.S.

Q Were all components necessary for the final assembly of the 7215 which is to be delivered to Dr. Klein completed in the United States, to the best of your knowledge and belief?

A Yes, to the best of my knowledge and belief, all the subassemblies required for Model 7215 for the units that either have been or will be delivered to Dr. Klein were manufactured in the United States."

MR. MALLOY: To page 330.

"BY MR. MALLOY:

Q So you expect to have a 7215 unit implanted in a human before any application for approval is filed with the FDA in the United States; is that correct?

A Yes."

**DAY 7 TRIAL TESTIMONY OF
JOHN KEIMEL
[page 144]**

Q Would you explain why?

A Well, we are currently spending quite a lot of money each year in design and development of the 7215 and before that the 7210. The current fiscal year that ends in May, for example, will find us approximately five and a half million dollars down. Previous years our spending has been approximately the same, about four to \$5 million per year over the last five or six years. And over that period of time, we have sold very few, relatively speaking, numbers of 7210 and 7215 devices, and I would be confused as to how we could be profitable in that respect.

Q Have you operated at a loss for that project?

A Yes. As I mentioned, this year we are operating at a loss of five and half million dollars, this fiscal year.

Q Mr. Keimel, continuing on with the PCD, 7215, would you please give us an overview technical description of how that device works. And if there are any demonstrative exhibits that you know of that we have here that you would like to ask for, would you please do so.

A Okay. That's the PCD 7215?

Q Yes. I would first like an overview technical description.

A Yes. It is a very complicated device and often times I don't know where to start.

Let me start off, then, by talking about the tachyarrhythmia control features of the device. In summary, it

**DAY 9 TRIAL TESTIMONY OF
DR. GEORGE KLEIN
[page 30]**

Mr. Johnson?

MR. JOHNSON: The defendant calls Dr. George Joseph Klein to the stand.

... GEORGE J. KLEIN, sworn ...

DIRECT EXAMINATION

BY MR. JOHNSON:

Q Dr. Klein, please tell the jury where you reside?

A London Ontario, Canada.

Q What is your current occupation?

A I am a cardiologist.

Q I am going to show you a copy of Trial Exhibit 1216. What is Exhibit 1216?

A It is my curriculum vitae.

Q Does it describe your accomplishments and awards and education accurately?

A Yes, it does.

Q Please describe your education after high school.

A I went to the University of Toronto, where I did an undergraduate degree. I graduated medicine in 1972. I did a residency training in internal medicine and cardiology at the University of Toronto between 1972 and 1977.

Between 1977 and 1979, I was a fellow in cardiology at Duke University in Durham, North Carolina. I then returned to University of Western Ontario in Canada on faculty in a division of cardiology.

[Klein — page 31]

Q Have you passed any specialty examinations?

A I passed the examination of the Royal College of Physicians and Surgeons of Canada in internal medicine and in cardiology and I am board certified in internal medicine and cardiology in the United States and I am a fellow of the American College of Cardiology.

Q Have you authored or co-authored any publications?

A Yes, I have.

Q How many and in what general subject matter areas?

A The publications are in the area of cardiac arrhythmias and techniques to terminate cardiac arrhythmias, and there are approximately 130 publications.

Q Have you additionally authored any abstracts?

A Yes. About the same number of abstracts.

Q And what is your current position again?

A I am an associate professor of medicine at the University of Western Ontario and I direct the arrhythmia laboratory at the university hospital.

Q Now, are you authorized by any government agencies to conduct clinical investigations?

A I am authorized by the Health Protection Branch in Canada and the FDA in the United States to conduct clinical — selected clinical trials.

Q Are you an authorized clinical investigator to implant the Medtronic Model 7215 device?

[Klein — page 32]

A Yes, I am.

Q Are you also authorized to implant the Intec CPI defibrillator?

A Yes, I am.

Q And have you in fact implanted either or both of those devices?

A Yes. We have implanted approximately 30 of the CPI devices and four of the Medtronic devices.

Q Do you know of any other physicians whose patients have received both the Medtronic, that is not the same patients, but whose patient population has received both the Medtronic Model 7215 and the CPI defibrillator?

A No. To the best of my knowledge, we are the only ones who have implanted both devices and had experience with both of them.

Q Were the Model 7215 units commercial units?

A No, they were not. They were implanted under an investigational or research protocol for compassionate use in patients who did not appear to have a viable alternate therapy.

Q What restrictions were placed on you by the Canadian government in connection with those implantations?

A The guidelines were that currently available devices or alternate forms of treatment were not satisfactory as the experimental device.

Q In connection with the implant that you did in Canada and

[Klein — page 33]

the 7215, did you do them in accordance with an FDA protocol?

A Yes. All the implants were done under strict research guidelines under protocol.

Q Have you signed an agreement called an investigator's Agreement with the FDA agreeing to be bound by those protocols?

A Yes, I have.

Q Now, in addition to being a clinical investigator, do you perform any consulting for Medtronic or any other company?

A Yes, I do.

Q About what percentage of your income do you derive from consulting for Medtronic?

A Approximately five percent or less of my income.

Q What are some of the other companies that you consult for?

A I consult with pharmaceutical industries, Noah Pharmaceuticals and 3M Corporation.

Q What do you do for 3M?

A They have a division, drug division named Riker Pharmaceuticals and I consult with them on their product, their anti-arrhythmic product.

Q What are the principal therapies which are provided by the Model 7215?

A The 7215 is an arrhythmia control device that has several functions. It has the capability to maintain heart rate at an adequate rate in case the heart rate becomes too low. A conventional pacemaker we all know about, have known about for

[Klein — page 34]

many years, is merely a little device that provides electrical impulses to the heart to keep the heart rate at an acceptable constant level, much like a thermostat. So first of all, it is a pacemaker, it is a pacemaker, a conventional pacemaker for bradycardia in a conventional sense.

Secondly, the device is also capable of treating very fast heart rhythm disorders by a variety of ways. We have several ways of treating very fast rhythm disorders. These can cause symptoms of dizziness, passing out or even death. We have several ways of dealing with those. One of the ways is to actually accelerate the heart artificially faster than the actual rhythm rate that the patient has spontaneously, and fortunately for us that in many instances stops the arrhythmia and brings things back to normal. We call that overdrive pacing or anti-tachycardia pacing. That is a painless method of stopping a fast heart rhythm problem and often it is even inperceptive, it is not perceptible to the patients.

Finally, for rhythm disorder really gets out of hand, the heart is racing so fast that nothing else seems to be able to bring it back to normal, we can apply a stronger electrical shock to the whole heart that essentially shocks it back to a normal rhythm with a single higher energy shock, much like a little explosion, if you will. It is not really an explosion, but it convulses the heart back to normal with a single high energy shock and we call that cardioversion or defibrillation.

[Klein — page 35]

So the device essentially does three things. It prevents the heart rate from going too slow; it can prevent rapid heart rhythm disorders by so-called pacing techniques or techniques that accelerate the patient's heart rhythm to stop their arrhythmia; and finally, if necessary, it can provide a higher energy shock to shock the heart back to a normal rhythm with a higher energy output.

Q In addition to the overdrive pacing that you mentioned, are there other therapies for treating the fast heart beats?

A Yes, there are. There are various ways of overdrive pacing. For simplicity, I don't think they are important to us, but there are various means of manipulating the patient's own heart rhythm during a fast heart rhythm disorder to bring it back to normal by the use of a pacing device which allows us to manipulate the heart rate.

Q In the Model 7215, is there just one pacing therapy for a fast heartbeat or are there several? Could you describe what's available in the device?

A There are an infinite variety of pacing techniques that one can try to stop a patient's heart rhythm disorder and they can be graded.

One can try a relatively simple therapy at first, a simple program, if you will, to bring the patient's heartbeat back to normal using manipulation of the heart rate. One can then become more aggressive and make it more rapid and more

[Klein — page 36]

complicated. Finally, if all that fails, one can induce higher energy shocks. Not only can one induce higher energy shocks, but one can induce higher energy shocks at a graded level.

For example, one can try a small shock at first, a relatively small shock that may not be as painful to the patient, and then if that doesn't work, you can try a larger shock to the maximum output of the device. So it provides an infinite variety of therapies

that one can apply to tailor to a given patient's particular rhythm disorder.

Q Who selects the therapies and how are they selected?

A The therapies are selected by the cardiologist who implant the device and we bring the patient — after the device is implanted, we bring the patient back to our laboratory, we turn off their rapid heart rhythm disorder by using the device. The device can actually be programmed to control the heart rate, so we can turn on the patient's own rhythm disorder and by trial and error, determine which is the safest and most pain-free way of bringing about cessations of this abnormal heart rhythm disorder.

Q You mentioned that you have implanted some 30 CPI defibrillators?

A Yes.

Q Could you compare for us your experience with the Medtronic Model 7215 and the CPI defibrillators, pointing out the advantages,

disadvantages and differences between the two units [Klein — page 37] from the physician's or patient's standpoints.

THE COURT: Well, may I see you.

(Whereupon, a discussion was held at sidebar on the record as follows:)

THE COURT: First of all, this sounds to me as though we are going to be comparing which is a better of the two devices, which I really don't think has any part of this trial, as I told Mr. Malloy on a couple of occasions.

MR. MALLOY: I agree, Your Honor.

THE COURT: Secondly, this sounds like it might be the sort of thing that comes within the public interest testimony that we talked about and it is for me rather than the jury. I just don't understand —

MR. MALLOY: I agree.

THE COURT: — why we want to compare the two devices. If we are saying this device is better or this is not as good —

MR. JOHNSON: Well, Your Honor, first of all, there has been a great deal of commercial success and these devices have been touted, and in fact I recall that Mr. Malloy's witnesses had direct comparisons which I complained about and he said no, they were appropriate to compare the two and in fact the testimony proceeded.

We have had direct comparisons before the jury in exactly the same issue.

[Klein — page 42]

MR. JOHNSON: Well, burst pacing is a tachycardia treatment.

MR. MALLOY: It is irrelevant.

MR. JOHNSON: It is absolutely relevant because they have alleged that they can come in and treat all this tachycardia and they can do great job and do it by delivering a whopping shock to people sometimes when they don't need it and I think the jury has every right to hear in its response to all these allegations of this great invention and how man kind has been helped by this. They have a right to see how this device works by comparison to what the CPI does. I think they ought to know and see how crude the CPI device is when it comes to treating tachycardia and what the effect is on the patients.

MR. MALLOY: Totally irrelevant, Your Honor. If they want to talk about their cardioversion and defibrillation with shock treatment, that's one thing.

THE COURT: No. I will overrule your objection, Mr. Malloy

(End of sidebar discussion.)

BY MR. JOHNSON:

Q Dr. Klein, I am going to repeat that question.

Without reference to the bradycardia pacing therapies that are provided by the 7215, would you please compare your experiences with the Model 7215 PCD and the Lilly CPI defi-

brillator as it relates to tachycardia therapies and [Klein — page 43] defibrillation therapies the two units provide, giving the advantages and disadvantages of each.

A Well, it is a little hard to compare them directly because actually the patients that we select for one are different than the patients that we have selected for the other. The older device, the older defibrillating device provided a shock to bring back heart rhythm disorder for a catastrophically fast arrhythmia. So the heart would start to race very, very quickly, the device would detect it and deliver a strong shock to the heart to bring it back to normal.

We have used that device in patients who are prone to develop these very rapid heart rhythm disorders, essentially ventricular fibrillation, that cause them to have symptoms very quickly, to have lightheadedness and to lose consciousness very quickly. This device will then shock them and bring the heart rhythm back to normal, and in summary, in that type of patient, our experience with the CPI device has been good in that it has fulfilled that function in a reliable way.

Now, however, we must remember that this device is essentially a one-trick pony. All it does is it shocks the heart back to normal. No matter what the fast rhythm disorder is, it is one answer to that, is a strong shock, which in a patient who is awake during the shock, if a patient doesn't pass out prior to the shock, the shock can be quite a traumatic experience, which varies from patient to patient, but some of [Klein — page 44] them find it very, very distressing. So it provides one therapy.

Now, there are another group of patients who will get very rapid heart rhythm disorders, but they are not quite as immediately dangerous as the group I have just described. They will get a very rapid heartbeating, but they won't pass out right away. Their blood pressure might drop a little and they may get a little lightheaded, but in general they will be able to tolerate their symptoms for a longer period of time and they are not in imminent danger of dying.

Now, this is that group of patients that we have selected for this other device, because for that group of patients, it is

really unacceptable to shock them each time they have one of these more moderate rapid heart rhythm disorders.

Q Excuse me. When you say the other device, would you tell the jury — be sure the jury knows which device you are talking about.

A I am sorry. For the group of patients that we have selected for the new Medtronic device, we felt that the CPI device was inappropriate, and the reason for that was that they developed frequent episodes of fast heart rhythm disorder that did not cause them to lose consciousness. Their hearts would race, they would feel bad, maybe a little lightheaded, but they could tolerate their fast heart rhythm disorder for a long time [Klein — page 45] without passing out or losing consciousness.

Now, for that group of patients, it would be almost unacceptable to have them shocked with a vigorous shock every time they got their rapid heart rhythm disorder. So for them we selected the newer Medtronic device which at first attempts to stop [sic] these rapid heart rhythm disorders with the more painless pacing techniques. That is — at first will try to accelerate the heartbeat beyond the patient's own heartbeat, in order to stop these rhythm disorders painlessly, and we can program this particular device to various therapies, as I explained before. We can try these pacing techniques, we can try a lower energy shock which might be less painful than a higher energy shock and only if all else fails does the new device resort to a more distressing high energy shock to stop the arrhythmia.

Q Doctor, is there any difference in the power levels that are inherently used and/or the safety relating to those levels between these two devices?

A The maximum output of the older CPI device is in the range of 30 joules, which is our unit of energy. The maximum output for the 7215 Medtronic in your device is in the range of 15 joules, so the max number energy for the newer device is approximately half of the older device.

How does this relate to safety? I think I can answer that

by describing how we decide when we put these products in

[Klein — page 46]

whether the energy is sufficient and the way we decide is on the operating room table with the heart beating and exposed, we make the heart fibrillate; in other words, using an electrical current, we make it race so quickly that it doesn't pump, it is in ventricular fibrillation.

We then, with the system that we are using, be it the older CPI device or the newer device, we then try to shock it back to normal using various grades of energy starting low and working our way up. The lowest energy that appears to consistently work we call the threshold energy.

So for the sake or argument in a given patient, we will try out one of the devices and find that we can consistently bring the heart back to normal with let's say five joules. If we then decide that our product has 15 joules, we then say that our margin of safety is at least threefold and that that device in that particular patient is acceptable.

If on the other hand, we find that we cannot defibrillate the heart unless we use 25 joules, then obviously that device is not acceptable for that particular patient. So the absolute energy of the device is not nearly as important as our so-called margin of safety.

For instance, if you can defibrillate with one joule, a unit of one joule, then there is not much point in putting a 30-joule device in, a 15 joule device is already sufficient overkill. It is like putting 100 horsepower into a lawnmower **[Klein — page 47]** when two horsepower will mow the lawn. So the margin of safety is more important than the actual energy output.

We prefer to use smaller energy devices if possible as a matter of choice because the size of the device is directly related to the battery. You may well say well, why don't we put in 200 joules in everybody. The higher the energy, the bigger the batteries that are required to power the device. The converse is true. The lower the energy that we can get away with, the smaller the battery and the more aesthetic the device, the more appealing

and the more easily one can implant it under a patient's skin. Ultimately we have to remember that this device has to go under a patient's skin and the bigger and bulkier the device, the less acceptable it is, especially to thinner patients and smaller patients.

Q Dr. Klein, are there any cost issues relating to the use of either of these devices?

A To the best of my knowledge, the cost of the two devices is comparable. They are both expensive.

Q Are these devices ever implanted along with other devices; that is, not just used alone?

A The older device —

MR. MALLOY: Your Honor, objection. I think we are getting into the territory that we talked about before.

THE COURT: Why don't you talk it over between yourselves and see if you can agree?

[Klein — page 49]

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. JOHNSON: Your Honor, I was about to ask the witness to describe the problems which result from pacemaker cardioverter interactions when the Lilly device is used with a separate pacemaker. We have had some testimony on this from I think it was either Dr. Luceri, I think it was Dr. Luceri and it is a significant disadvantage because of the problems which result from having shocks applied to patients when they shouldn't be applied or perhaps even missing events, that is missing things that ought to be treated which aren't treated.

MR. MALLOY: That's pacemaker. It is not relevant.

MR. JOHNSON: Well, I think it is directly relevant and it certainly is relevant to the patients, the ones who aren't getting treated or who are getting treated, and I think this is another aspect and they also, in this case, now are saying pacemakers are irrelevant, but if you will recall on the damage case, they

made a great deal out of the fact that this had turned around their business and their pacemaking business in going crazy and that this was part of the damage thing and I don't see why this isn't a perfectly appropriate inquiry, because it is a very real part of the way the device is used.

MR. MALLOY: It is totally irrelevant.

THE COURT: What fact does it go to prove it is an issue, Mr. Johnson?

[Klein — page 50]

MR. JOHNSON: It goes to show that the commercial — first of all, the damages side, that the commercial success that they are getting may come from use of pacers, but I think more importantly, it goes —

MR. MALLOY: Commercial success of whom?

MR. JOHNSON: Of CPI. We are talking about the separate pacing units which would have to be implanted.

MR. MALLOY: You just turned yourself upside down.

MR. JOHNSON: No. We are talking about that, but I am also talking about the fact that the Lilly defibrillator once again does not have the ability to reliably treat patients who also need separate pacing units. The reason is because it applies shocks which are inappropriate because it is listening to the pacer instead of listening to the patient or it shock applies shocks which are inappropriate because it is listening to both the patient's heart and the pacer or because it is listening to the pacer and not listening to the patient's heart, it thinks everything is okay when in fact the patient could be in fibrillation.

This is a critical part, a critical piece of evidence to rebut their commercial success, the long felt want. It gives a basis for the reasons of skepticism expressed by others that they have relied on to try to prove unobviousness of the invention. All of this is rebuttal to what they have presented.

[Klein — page 51]

THE COURT: All right. I will permit it.

(End of sidebar discussion.)

BY MR. JOHNSON:

Q Dr. Klein, are the Lilly or CPI defibrillators sometimes implanted together with other devices?

A Yes, they are. They are often implanted together with ordinary pacemakers. As I mentioned, sometimes ordinary pacemakers are required to keep the heart rate from going too slow. They are also sometimes implanted with so-called anti-tachycardia pacemakers or that is the special pacing that I described which will accelerate the patient's own heart rate above the heart rate of the rhythm disorder in order to stop it painlessly.

So that in point of fact, the functions of the new device, the Medtronic 7215, are all there and other devices are not necessary with it, but with the older device, as I said, since it is only a shocking device, will also occasionally need another pacemaker to — for slow heart rhythm disorders or a specialized pacemaker to stop very rapid disorders, all of which are included in the new device in itself.

Q Dr. Klein, are there disadvantages in using multiple devices in the same patient, that is, the Lilly defibrillator along with these other types of pacemakers you have mentioned?

A Well, I would say yes, there are disadvantages. The first disadvantage is the cost, the cost of having two expensive [Klein — page 52] devices rather than just one expensive device.

The other problem is that at this point, the two devices were not made with compatibility, particularly in mind, so that one has problems with the function of one device perhaps interfering with the function of the other device.

Q How do those functions interfere, if they do?

A Well, one possible cause of interference is that —

MR. MALLOY: I am going to object to "possible," Your Honor. I don't know if we are testifying about fact or opinion here.

THE COURT: Well, I will let Dr. Klein describe the interferences that he has observed.

I don't think we are interested in remote possibilities, but I will certainly permit you to describe the ones that you observed yourself, Dr. Klein.

THE WITNESS: Since we have not implanted the two together, I can't comment on my personal experience. If I may rephrase that to say —

MR. MALLOY: Your Honor, I object to continuing comments of the witness, and I don't mean to interrupt—

THE COURT: Let me hear what he is going to say.

MR. MALLOY: Okay.

THE COURT: How are you going to phrase it, Dr. Klein?

THE WITNESS: How about an interaction that has been observed in the literature between the two devices?

[Klein — page 53]

MR. MALLOY: Well, Your Honor, this goes beyond what we had and I think he is here to testify about his own experience.

MR. JOHNSON: Your Honor, he is an expert and the other experts have testified throughout the trial based on their knowledge of the literature.

THE COURT: No, I will permit it.

THE WITNESS: An ordinary pacemaker or pacing device puts out electrical impulses. These electrical impulses can be — can fool the other device into thinking that the heart rate is racing faster than it actually is going, so one device is there pacing the heart, but yet the other device cannot distinguish between that device pacing or artificially [sic] stimulating and the patient's own intrinsic heart rate. So it can be fooled into

delivering shocks inappropriately when in fact the patient's heart rate is not in a ventricular fibrillation.

BY MR. JOHNSON:

Q Are there any adverse or adverse psychological effects that you have observed from use of the Lilly or CPI defibrillator?

A We have observed adverse psychological effects with any device that uses high energy shock on a consistent basis. In one particular patient with the CPI device, we actually had to explant the unit and resort to cardiac transplantations because this patient became psychologically totally disabled by the

[Klein — page 54]

fear of getting shocks, which to him were very uncomfortable, so this patient would just sit in his room all day afraid to move for fear that this device would set off a shock in his chest, which caused a great pain to him.

So I think that it is very, very important in these patients to try to treat the patient with a painless therapy and only resort to the shocks if absolutely necessary, and I think everyone in this field agrees to the importance of trying to treat patients, if possible, with painless pacing therapies and resorting only to the more psychologically traumatic and painful shocks, if necessary.

Q I would like to direct your attention to the particular patients who have received the 7215 PCD. Would the CPI defibrillator have been a better choice for these patients?

A No. In the four patients that we chose, as I pointed out before, their problem was not this immediate catastrophic ventricular fibrillation that caused them to lose consciousness and for which they required an immediate shock. Their problem was a less pronounced tachycardia or fast heart rhythm disorder which did not cause them to lose consciousness. They felt bad, they had to go to the hospital to get it treated, but they were perfectly awake and alert. Some of them were experiencing their fast heart rhythm disorder once every two days, so to put the alternate device in would require a strong shock in the chest to them every second day, which would not only create [Klein — page 55]

psychological mayhem, but would also deplete the device in a very short time.

So in that particular patient in particular, it was very important to implant the device that would stop the rapid heartbeating disorder by alternate pacing techniques and resort to the shock only if absolutely necessary. And it is fair to say that all four patients fit those criteria of having rhythm disorders, although very serious, but having rhythm disorders that left them relatively alert and conscious during the therapies.

Q Could these patients have been adequately treated just with drugs?

A Aggressive drug trials with one or more drugs at a time failed to successfully control their rhythm disorders. They all had very serious cardiac problems.

Q What were the other available treatments for these patients besides the Medtronic Model 7215?

A The only realistic alternatives in our patients were heart transplantations or the use of the CPI device in conjunction with other sophisticated pacing devices. We don't like to do cardiac transplantations except as a last resort. The waiting lists for that are just horrendous, there are other problems, so that realistically our alternatives were between the 7215 and a CPI device in conjunction with another specialized sophisticated pacemaker. So we chose the newer device which [Klein — page 56] incorporated everything into the unit, the original unit.

Q What was the prognosis for these patients without the treatment that they received?

A The long-term outlook of these patients was not immediately that grim. In other words, they did not have a total cardiac arrest, as I explained, every time they got their fast heart rhythm disorder, but nonetheless, they were very disabled and they had to make frequent trips to the hospital. The last gentleman that got the 7215 had been in a hospital for approximately four months without being able to get out of the hospital, because of getting this problem every second day, so I think the prognosis for a relatively rehabilitated life in these patients was almost zero.

Q Are all of the patients who received the 7215 device still alive?

A No, they are not. One patient has died.

Q Did this death have something to do with the Model 7215?

MR. MALLOY: Maybe the other way around.

THE COURT: I am sorry?

MR. MALLOY: Maybe counsel meant to ask it the other way around.

MR. JOHNSON: I am sorry. I did mean to ask it the other way around.

BY MR. JOHNSON:

Q Did the Model 7215 have anything to do with this death?

[Klein — page 57]

MR. JOHNSON: Thank you, counsel.

THE WITNESS: No. I don't believe that the Model 7215 had anything to do with the death.

BY MR. JOHNSON:

Q Okay.

A If I may qualify that, as I am sure I will have to sooner or later, the device — the patient — this patient died. This patient had previous suicide attempts and was very psychologically disabled from his problem. In fact, several months before we put this device in, this patient was so despondent that he overdosed on two very toxic cardiactive medications, one of them being Digitalis and one of them being a drug called Sedalone (phonetic). The patient came to the emergency room close to death with low blood pressure and a very slow heart rate. At the time of this patient's actual death, he had toxic levels of the drug Digoxin in his body which were twice the upper limit of the acceptable level, so he had undoubtedly again overdosed. The mode of presentation the first time he overdosed was low blood pressure and slow heart rate, so I think that my best estimate of the cause of death was that the same thing happened.

When we talk about the device being implicated in death, we are talking about two potential ways it could be implicated. One potential way that a device can cause a death of a patient



is to go off inappropriately. So in other words, [Klein — page 58] when there is nothing wrong with the patient, this device can just go haywire and cause the patient's death by creating more problems and more mayhem than is present. That's one cause of death. That did not happen with the 7215 because we can interrogate the device, we can put a little receiver over the device and the device tells us the events, at least the cardiac heart rates at the time of any therapies and it also accurately records the therapies that it gave. So the device did not kill the patient. We know that because we can interrogate the device and the device did not go off to create any problems.

The second way a device can be implicated in the death of the patient is if the device fails to treat a therapy, fails to treat rather a rhythm disorder — for instance, in order to treat a rhythm disorder, these devices have to constantly sense the heart rate, so there is essentially a sensor there to tell it what the heart rate is. So if one says well, is it possible that this man had a rapid heart rate in which the sensor function of the device didn't work, I would have to say yes, that's certainly a possibility and that's always a possibility in any patient who has any of these devices.

Q Just so your testimony is clear, is it still your opinion then that the death was unrelated to the use by the patient in the 7215?

A That is my opinion and that was the official report as the cause of death. The official cause of death was written by the [Klein — page 59] pathologist involved in the case who was not related to our team, but the pathologist doing the case was a pathologist in Toronto. Our hospital is in London. The official cause of death cited by the pathologist at the other hospital was drug overdose.

Q How many of the remaining patients still have the Model 7215 PCD implanted?

A Two of the three remaining patients still have a Model 7215. One of the patients — I must point out that when a patient has heart problems, there are two general categories. One is the heart has to work as a pump, so in other words, it has to pump

blood to keep us breathing and to keep us from getting swelling and keep us moving around. The other function of the heart is electrical and that's to keep the rhythm in order. Any of these devices, at best, they just hope to keep the rhythm in order. In this particular patient, the device worked very well and kept the patient's heart rhythm in order and he did not get any abnormal heart rhythms that weren't treated.

On the other hand though, this patient had very bad heart disease and his heart as a pump had totally deteriorated in the interval between the time that we had implanted the device and the actual time of the transplant. So in other words, he had a progressive deterioration of his heart as a pump, so that at the time of the transplant, he was essentially [Klein — page 60] only running on half a cylinder, even though the electrical system was intact. So the reason for transplantation had nothing to do with the device, it had to do with the deterioration of the patient's heart as a pump.

The other two patients are doing very well. They are both using the painless treatments for their fast heart rhythm disorder quite frequently and they are not aware that their heart rates are going fast and being treated. And one of these patients is the one that had to sit in the hospital in Detroit for four months without being able to go home prior to getting this device.

Q Do you have other patients in your patient practice that could benefit from devices such as the Model 7215?

A Yes. We are a referral center for patients with arrhythmia problems and I would estimate that we would implant perhaps 50 of these devices every year if they were available to us readily.

MR. JOHNSON: Your Honor, I think we have reached the point here you—

THE COURT: All right. Members of the jury, this would be a good time for us to take a brief recess, so can we take about five or ten minutes, please.

(Jury out at 11:10 a.m.)

THE COURT: Let the record reflect that we have excused the jury, please.

[Klein — page 61]

BY MR. JOHNSON:

Q Dr. Klein, is there an ongoing need for devices such as Medtronic's Model 7215?

MR. MALLOY: Excuse me. I know the jury is absent, but if we could have non-leading questions, I still think that would be better.

BY MR. JOHNSON:

Q Dr. Klein, what is the need, if any, for the devices such as the Model 7215?

A I think the need for devices such as the Model 7215 is enormous. The CPI device, the original device really showed us the potential for treating patients with electrical devices and the advantages of this particular electrical device and newer generations is enormous. There are so many patients out there with serious heart rhythm disorders that require this therapy.

A few years ago we had a wave of enthusiasm for surgical treatment of these cardiac rhythm disorders, but unfortunately most of the patients who have this problem have such severe heart disease that the mortality — the survival of surgery is often exceedingly low. Many times the heart function is so badly compromised, so badly damaged that all our anti-arrhythmic drugs fail to help these patients, so that the development of sophisticated and very versatile devices to treat these problems is enormously important and I think that the more people that get into the fray to give people these [Klein — page 62] devices, the better off everybody will be.

Q Is there a public interest in having more than one company experiment in this area in your opinion?

A Well, I think that with the natural history of any product, once there is intense competition and many, many independent efforts to come up with better products, that's when we traditionally evolve cheap products, effective products and we develop innovative ideas and newer ways of dealing with old problems.

Q Is there any public interest in proceeding with experimental investigational studies of the type that you are working on?

A Well, I think it is enormously important to the public. The four patients that we used the Model 7215 in we felt that it was the only realistic available option to them, and there are many more patients out there other than the four that we have implanted. In fact, the investigators for this device have been complaining to get these devices for their patients and they have been limited by device availability.

MR. JOHNSON: Your Honor, I have no further direct examination.

MR. MALLOY: Could I cross him on this and then we will go back to the other?

THE COURT: Sure.

CROSS-EXAMINATION

[Klein — page 98]

Q Doctor, was there any implication of alcohol use with this particular patient Mr. Malloy has been asking you about?

A If I am not mistaken, an empty 40-ounce bottle of Southern Comfort was found at his bedside when he died, so we also — that alcohol was implicated in the cause of death of this patient.

BY MR. JOHNSON:

Q Was an alcohol level actually found at autopsy in the blood?

A I don't recall. I am sure that's in the record.

Q Don't you still have the letter in front of you?

A Oh.

Q Please look at D-11.

A D-11.

Q Pages D-11.

A 732?

MR. JOHNSON: Tim, did you take the letter back from the witness?

MR. MALLOY: Here, you are. No, I didn't but you are welcome to my copy.

THE WITNESS: Yes, I have it here. The alcohol level was 111 millimols and toxicity would be seven millimols per liter, so there was evidence of excessive alcohol, although it was not — it could not be considered high enough to be the cause of death by itself. It was high enough to be a [Klein — page 99] contributing factor.

BY MR. JOHNSON:

Q And what was the Digoxin level?

A The Digoxin level was 4.37 millimols per liter and the upper limit of normal is 2.56, so just about twice the upper limit of acceptable.

Q Was there any abnormal liver indicated that would be consistent with heavy drinking?

A The patient's liver was very —

MR. MALLOY: Your Honor, I am going to object. He has already indicated that it wasn't the cause, so I think we are belaboring —

THE COURT: No, I will permit it. Overruled.

THE WITNESS: The patient's liver was severely cirrhotic due to his long standing problem with alcohol and psychological problems. Cirrhotic means alcohol scarred.

BY MR. JOHNSON:

Q Now, I would like to direct your attention back to a few of the other matters that were raised by Mr. Malloy. He asked you, I think, could the Model 7215 be operated with sequential pulse or without sequential pulses. Does the protocol that you follow indicate how it is to be operated?

A I believe that the protocol is to use sequential pulse defibrillation.

Q And you followed the protocol?

[Klein — page 100]

A That's correct.

Q And does the protocol indicate the types of electrodes that you are to use?

A It does indicate the types of electrodes. We have some option as to size.

Q Are they always patch electrodes?

A They are patch electrodes.

Q And you have always followed those protocols, haven't you?

A Yes, we have.

Q Now, you referred to constantly sensing in your testimony on your cross-examination. Do you know what the device does when the capacitor charges in that regard?

A The capacitor charges, that means that the battery is getting ready to deliver a charge, so at that time the device, to the best of my ability — again, I am not an engineer — but to the best of my ability, while the battery is charging, there is so much electrical noise that it is almost impossible to be able to sense properly to detect properly, so during the time that the battery is actually charging, the monitoring functions of the device temporarily cease.

MR. JOHNSON: I have no further questions.

RECROSS-EXAMINATION

BY MR. MALLOY:

Q Doctor, isn't it the fact that you and others have experienced that sequential pulse has operated on many

[Klein — page 103]

Q By Medtronic?

A By Medtronic, that's correct.

MR. MALLOY: Thank you.

MR. JOHNSON: No further questions.

THE COURT: All right. Thank you, Doctor.

(Witness excused.)

MR. JOHNSON: Your Honor, our next presentation is a videotape deposition of Dr. Zacouto. We can start it now or we could take an earlier lunch and start it after lunch.

THE COURT: Well, this is one of those days when I can't come back until 2 o'clock, so at least if we can get it started, I think that may be helpful.

MR. MALLOY: Could we approach the bench, Your Honor, with a small point.

THE COURT: Certainly.

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. JOHNSON: Your Honor, I don't have any problem with this paragraph. This paragraph begins to get into an instruction which is far beyond the scope of what we are talking about. However, we start here in the second paragraph, two begins, "Whether the patents are valid or invalid depends on a comparison," and then I would suggest that the problem with this portion of the instruction is that it seems to suggest to the jury, this particularly alleged existence

**DAY 13 TRIAL TESTIMONY OF
JAMES VEALE
[page 35]**

... JAMES RANDALL VEALE, sworn ...

DIRECT EXAMINATION

BY MR. LEVIN:

Q Mr. Veale, would you please state your full name for the record?

A James Randall Veale.

Q What is your current profession?

A I am a consultant in the regulation of medical devices about Food and Drug Administration.

Q And where is your business located?

A In Attleboro, Massachusetts.

Q Could you tell us what degrees you received after high school?

A 1966 I received a bachelor's degree in electrical engineering.

THE COURT: Mr. Veale, try to keep you voice up. I want you to talk towards the jury but it would be helpful to me if you would talk good and loud because I am not going to be able to see your face.

THE WITNESS: I will certainly try. 1966 I received a bachelor's degree in electrical engineering and in 1972 I received a master's degree in electrical engineering.

BY MR. LEVIN:

Q Could you recount for us your professional career.

[Veale — page 36]

A After getting the bachelor's degree in electrical engineering in 1966, I was with the Air Force for four years as an electronics engineer.

In 1970 I left the Air Force as a captain, went back to graduate school and studied biomedical engineering and electrical engineering.

In 1973 I joined the Food and Drug Administration as a biomedical engineer as part of a staff that the Food and Drug Administration was assembling to help them set up regulations for the regulation of medical devices.

In 1977, while at the FDA, I was appointed a division director responsible for the review and approval of new medical devices that were being submitted to FDA for approval.

At the end of 1984, I left FDA and became a consultant and have been consulting in the regulation of medical devices and FDA's requirement for medical devices since.

Q As part of your work at FDA, were you involved in the review of IDE or PMA applications relating to medical devices?

A Yes, I was.

Q And approximately how many IDE applications did you personally review during your period with the FDA?

A While I was at FDA either I personally reviewed or I supervised the staff who reviewed several hundred IDE's. I don't remember the precise number.

Q Did any of those IDE applications concern implantable

[Veale — page 37]

medical devices?

A Yes. Yes, they did.

Q Do you recall approximately how many there were?

A Again, I don't know the precise number, but it would be at least 25 and probably as many as 50.

MR. MALLOY: One short point. May we approach the bench, Your Honor?

(Whereupon, a discussion was held at sidebar on the record as follows:)

MR. MALLOY: The thought just struck me, and it may be that this is not even going to be pertinent, but I think it would be inappropriate if he is going to testify as to any actual personal experience or supervisory contact with any of the applications that are involved in this case.

MR. LEVIN: He is not.

MR. MALLOY: Okay.

(End of sidebar discussion.)

BY MR. LEVIN:

Q During your period with the FDA, did you personally supervise the review of any PMA applications?

A Yes, I did.

Q And approximately how many PMA applications were there?

A Again, either I personally reviewed or I supervised a staff that reviewed probably 25 or 30 premarked approval applications.

[Veale — page 38]

Q And did any of those involve implantable medical devices?

A Yes. Quite a number did.

Q Could you tell us what kind of implantable medical devices?

A They were a wide variety of implantable devices, varying from such products as plastic implant to implantable neuro-stimulators, a type of pacemaker that's used for stimulating the nervous system.

Q I would like to show you what we have marked as Trial Exhibit 1215 and ask you whether that is a copy of your curriculum vitae?

A Yes, it is.

Q And have you published any papers regarding the regulation of medical devices by the FDA?

A Yes, I have.

Q Are those papers listed on your CV, Trial Exhibit 1215?

A Yes. This is correct.

Q Mr. Veale, in general, is the distribution of medical devices regulated in the United States?

A Yes. The distribution, sale and clinical application or clinical use of medical devices is regulated in the United States by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. That was amended in 1976 to extend extensive authorities over medical devices.

Q Now, are implantable cardioverters and defibrillators included within these kinds of regulating medical devices?

[Veale — page 39]

A Yes, absolutely. These devices, implanted cardioverters and defibrillators, are considered to be class three devices and are regulated the most — in the most strict fashion by FDA.

Q Can you give us a general overview of how the FDA regulates medical devices such as implantable cardioverters or defibrillators?

A Well, first these kind of devices, these lifesaving implantable devices have to be approved by FDA before they can be marketed. Even before they are approved for marketing, they are required by FDA to undergo fairly extensive clinical evaluation using human subjects. The experimental testing in human subjects itself has to be approved by FDA as well.

MR. MALLOY: Your Honor, I am going to object at this point as to whether or not the witness is testifying on his own personal involvement or simply as an after-the-fact expert and I think that ought to be brought out, because if it is personal involvement, I certainly have an objection.

MR. LEVIN: May we approach the bench, Your Honor? I thought we —

MR. MALLOY: I don't think it is —

THE COURT: Talk it over with each other.

(Whereupon, a discussion was held among counsel off the record.)

BY MR. LEVIN:

[Veale — page 40]

Q Mr. Veale, while you were with the FDA, were you personally involved in an IDE or PMA application relating to any implantable cardioverter or defibrillator by Eli Lilly, CPI or Intec?

A No, I wasn't.

MR. MALLOY: Or Medtronic.

BY MR. LEVIN:

Q Or Medtronic?

A No, I wasn't.

Q And during the period of your outside consultantship, which I believe you testified has been within the last year or so, have you been so involved?

A No.

Q I believe you testified that before a medical device can be sold in the United States, certain approvals are needed and before it can be tested in the United States, certain approvals are needed. Do these approvals have a specific designation within the FDA?

A The pre-market approval application is referred to by — as a PMA application. This application must be submitted to FDA after the device has been tested and before FDA will permit it to be marketed in the U.S.

Q What about the testing period that you referred to?

A During the testing period, that is during the period that is being evaluated in human subjects, the FDA requires that an

[Veale — page 41]

application referred to as an Investigational Device Exemption application or an IDE be submitted and approved by FDA. The IDE, when approved by FDA, limits the number of subjects and the number of hospitals or centers that the device can be implanted in and tested in.

Q Now, is there a particular application in which a company must make for an IDE?

A It is called an IDE application. It consists of information about the device, describing the design of the device and how it is built, the manufacturing information. It includes reports of all previous testing that was conducted on the device, that is all animal testing, laboratory testing and in some cases,

if it has been used in foreign countries, summary of the clinical uses in other countries.

It also includes a description of the investigational plan for the device, that is the procedures that will be followed in studying the device and the controls that will be taken to protect the patients during those trials.

Q And once an IDE issues, what happens?

A Well, once FDA approves the IDE application, then that gives the company the right to begin human trials or human testing of the device and they can proceed to do so. Typically, FDA will limit the number of subjects that can be — in this case, implanted with a device, and often the number of hospitals or centers that can take part in the study, but after [Veale — page 42] FDA approval of the IDE, then the company can proceed with the testing.

During the study typically the company will be required to report — submit progress reports to FDA as to how this study is going and they are allowed to proceed until they have accumulated sufficient data to demonstrate the device is safe and effective.

Q Now, during and IDE period may a company sell one of its investigational devices?

A A company can charge for the device, which is, I presume the same as you mean they sell. In other words, they can recover cost for the device. The cost can exceed the amount necessary to recover the research of cost that went into the device and the handling and the cost of the investigation itself.

Q Now, once the IDE data has been compiled, what is the next step in obtaining a PMA for a device such as an implantable cardioverter or defibrillator?

A Well, assuming the study went well and the data supported, the company would be expected to submit a pre-market approval application to FDA in which they would summarize the data, present all other animal and clinical data that they have accumulated, they would describe all of the manufacturing methods that are proposed to be used in making the device, they

would fully describe the technical details of the device, how [Veale — page 43] it is made, and they would provide a copy of the labeling and the operation of manuals that will be provided with the device.

Q Approximately how long is an IDE test period for a device such as an implantable cardioverter or defibrillator?

A Well, for a device like an implantable cardioverter or defibrillator, the test period would typically be, in my experience —

MR. MALLOY: Excuse me.

THE WITNESS: Two to three years.

MY MALLOY: I am going to object, Your Honor. We had testimony that this witness had no personal experience with this device. I think it is improper for him now to test about personal experience and his timing with this very device.

THE COURT: No, overruled. I think he has shown his expertise. If you want to ask him some questions about his background and qualifications, I will permit you to do that.

MR. MALLOY: I have a different — may I approach the bench?

THE COURT: Why don't you talk it over with Mr. Levin first.

(Discussion between counsel off the record.)

MR. MALLOY: Your Honor, I have a different objection and that is the question was "like implantable defibrillators," that's vague and indefinite. I think what Mr. Levin may have intended to say is some other device, not an implantable [Veale — page 44] defibrillator. I object to the vague and indefiniteness of "like an implantable defibrillator." If he wants to specify —

THE COURT: Well, Mr. Veale said, as I understood it, that an implantable defibrillator would come within a certain category, I forget what category it was, and I thought it was in that context that he was being asked a question. In other words, if it is category A, if implantable defibrillator is in category

A, what happens as far as category A is concerned. I don't believe that he has said that he can predict with absolute certainty that this device will have to be tested for 600 days plus 23 hours and 14 minutes. He hasn't come down with that, nor could anybody, but I think within the context of his testimony, the question is proper.

MR. MALLOY: Just so we understand he is not talking about personal experience with an implantable defibrillator.

THE COURT: All right.

MR. LEVIN: He has already testified to that.

MR. MALLOY: Okay.

BY MR. LEVIN:

Q Mr. Veale, I will repeat the question. How long is normally required for an IDE testing period for an implantable device such as a cardioverter or defibrillator?

MR. MALLOY: Well again, I am going to object, Your Honor, Cardioverter, defibrillator.

[Veale — page 45]

THE WITNESS: In my experience —

THE COURT: No, I will overrule your objection.

THE WITNESS: In my experience, I would expect the test period to require two to three years.

BY MR. LEVIN:

Q Is that because a device such as an implantable cardioverter or defibrillator is in class three as you have testified?

A It is because of the fact that it is a critical lifesaving device and also because it is considered a class three device, but primarily because it is of the nature of a lifesaving device and has to be exhausted of the testing.

Q And approximately how long does the FDA's review of a PMA application for a lifesaving class three device of this sort take?

A The FDA's PMA review process will almost always take at least one year from the time the application is first submitted until it is finally approved. For a product like this where FDA would be expected to extend an extensive amount of review to make sure the device is safe and effective, I would expect it to take longer and possibly as long as two years.

Q So then if a company wishes to ultimately market a class three medical device, it must first apply to the FDA for an IDE period of testing and after which it can apply to the FDA for a PMA?

[Veale — page 46]

A That's correct.

Q Each of which period requires some certain amount of time?

A That's correct.

Q In general, approximately how long would it take from the time the IDE is first granted until a PMA is obtained?

A For a product like the implantable cardioverter defibrillator, which is a lifesaving device, I would expect the entire process to take a minimum of three years and probably five or six years — five years or longer.

Q Would it make a difference in the FDA's deliberations or approval process whether the company which has filed for an IDE or a PMA has a patent license on its medical device?

A It would make absolutely no difference.

Q In general, does the fact that one company has received a PMA on a particular medical device make a difference to a second company seeking approvals of its own medical device? And let me restrict my question to class three devices.

A Well, in general, no, it makes no difference whether one company has received a PMA for a device or not. Each company must establish and submit a separate application for their own device.

Q And that means that a second company coming down the pike would have to go through the entire IDE testing and PMA application procedure?

A That's right.

[Veale — page 47]

Q Are you familiar with the term piggy-backing?

A Yes, I am.

Q And what does that term mean in FDA parlance, if anything?

A This would mean one company who is submitting a pre-market approval application or using the data that was previously submitted by another company on another product and using that data to support safety and effectiveness of their own product.

Q And is piggy-backing allowed within the FDA for class three devices?

A Well, for products that are required to go through the pre-market approval process, using data on another application on another device, this specific is specifically excluded. It is not allowed.

Q Are there any circumstances under which one company can use data already submitted by another company relating to a class three device, for example?

A The only instance that I would know would be if a second company bought the product from the first company, lock, stock and barrel. That is they bought the entire device, the entire technology, and proposed to produce the identical device and in effect they would be buying the pre-market approval application from the company as well.

Q In preparation for your testimony today, did you review any documents submitted to the FDA by Medtronic in order to receive an IDE for its Model 7215 PCD?

[Veale — page 48]

A Yes, I did.

Q I would like to show you Exhibits 1400, 1404 and 1405. Can you tell us what these exhibits are.

THE COURT: Give me the numbers again.

MR. LEVIN: 1400, 1404 and 1405.

THE WITNESS: These documents are the investigational device exemption application, the original application that was submitted by Medtronic for the Model 7215, an amendment to that application that was submitted by Medtronic on the same device and a supplement to that IDE application that was submitted by Medtronic.

BY MR. LEVIN:

Q Do these documents describe the design and operation of the Model 7215 device?

A Yes, they do.

Q And in preparation for your testimony today, did you review any documents submitted to or issued by the FDA which described the design and operation of Lilly's approved AICD product?

A Yes, I did.

Q I would like to show you Exhibits 1118 and 1438, and I will ask if you can identify those exhibits?

A This document is the summary of safety and effectiveness data that's issued by the Food and Drug Administration when they approve the automatic implantable defibrillator system pre-market approval application submitted by Cardiac [Veale — page 49] Pacemakers, Incorporated.

Q Which exhibit number is that document?

A 1438.

Q And what is Exhibit 1118?

A This document is the physician's manual for the CPI automatic implantable cardioverter defibrillator.

Q Are these the documents which you referred to as describing the design and operation of Lilly's approved device?

A Yes.

Q Assume, if you would, that the Model 7215 device was being developed not by Medtronic, but by Lilly. Could Lilly then rely on any of the data already submitted for its approved AIC device?

A No, they couldn't.

Q Any why is that?

A They are different devices. FDA would view them as completely different designs and completely different products requiring completely separate sets of clinical data to support their safety and effectiveness and different pre-market approval applications.

Q Well, what is the basis for your view that the FDA would view these devices as completely different?

A Well, they are different in electronic design and they also differ as far as the way they function; that is, they detect cardiac arrhythmias in a different way and they respond to [Veale — page 50] cardiac arrhythmias in a different way.

Q I would like to show you one more document I will place on the table there, Trial Exhibit 1426. Can you identify this document?

A This is the approval letter or actually a conditional approval letter issued by the Food and Drug Administration to Medtronic for the Model 7215 device?

Q You said Model 7215 device?

A Yes.

Q And have you reviewed this document in preparation for your testimony today?

A Yes, I have.

Q In preparation for today's testimony, have you also reviewed Trial Exhibit 755 which I will show you a copy of now?

A Yes, I have reviewed this document.

Q Can you tell us what that document is?

A This is the affidavit of Mr. John G. Keimel.

Q A Medtronic employee?

A Yes.

Q And in preparation for your testimony today, have you become aware of whether or not Medtronic has undertaken any implant in the United States pursuant to its conditionally approved IDE?

A Yes. According to Mr. Keimel's affidavit, there have been no implant in the United States of the Model 7215 under their [Veale — page 51] IDE, their approved IDE application.

Q Now, based upon your review of these documents and the other pile of documents that's sitting on the table there, do you have an opinion as to the time in which Medtronic is likely to receive full PMA approval for its PCD device?

A Well, considering the fact that they haven't started their clinical study yet and considering the fact that their IDE is limited to a maximum of 30 subjects at this point, my opinion is it will take them at least three and probably five or more years before they will be able to obtain final approval for their pre-market approval application.

Q And does the scope of this conditional IDE approval enter into your opinion?

A Certainly. They are only approved to implant the device in a total of 30 subjects and they will undoubtedly need several hundred subjects before they can obtain pre-market approval application, pre-market approval from FDA which means they will have to resubmit an IDE application at a later date to extend the study.

Q So then it is your opinion that Medtronic is unlikely to receive full pre-market approval opinion for at least three years?

A At least three years, yes.

MR. LEVIN: Thank you. I have no further questions.

CROSS-EXAMINATION

[Veale — page 60]

(End of a sidebar discussion.)

BY MR. MALLOY:

Q I want to ask you questions, Mr. Veale, about what is included in the term commercialization and what is not included in the term commercialization. Now, during the IDE proceeding, do you believe that Medtronic would be allowed — you have indicated that they shouldn't be allowed to commercialize; is that correct?

A Well, what I said is that the IDE regulation prohibits commercialization during the investigational stage.

Q Okay. Now, let's explore that term commercialization. Do you believe that under that provision that Medtronic would be able — would be allowed to charge a price for the PCD 7215 system in such a way as to allow head room for device improvements?

A I don't know that that specific reason would be suitable for justifying to FDA that a specific cost would be permitted.

Q Do you think that Medtronic would be allowed for their 7215 to price their structure in such a way as to allow competitiveness with the existing CPI unit called the AICD?

A Those aren't conditions that FDA would consider in supporting the cost.

Q Are you saying that would be impermissible?

A Those aren't the criteria that FDA review as far as the justification for the cost that's to be charged.

[Veale — page 61]

Q So that would be permitted under the FDA proceeding; is that correct?

A I am not saying that. What I am saying is that the criteria that FDA asks for would not include that.

Q Well, let me ask it this way: If the party came in, the second party, you have got one unit approved already, and then a second party came in with a similar unit, and revealed to you, to the FDA that they were going to charge a price and that they were going to set the price in such a way as to allow competitiveness with the existing already approved CPI unit, would that be permitted, if you knew that fact?

A I don't think that would be permitted as a justification for charge.

Q Now, if the party came in, in Medtronic came in and told you that the price they were going to set for their IDE unit, the PCD 7215, was going to be marginally premium priced compared to the competitive unit, the CPI unit, if you knew that fact, would that — would Medtronic be permitted to do that?

A The cost of competing units, as you put it, has no bearing on the cost of FDA approval or not.

Q So if you knew that fact, you would still permit Medtronic to go ahead and price their unit in such a way as to allow premium pricing compared to the competitive unit?

A If the costs are justified in terms of how much it cost to [Veale — page 62] run the study and how much it costs to produce the device, FDA would permit it.

Q Would Medtronic be allowed to come in under the IDE and set up — reveal to you that they are going to set a price for their unit, their IDE unit, called the 7215 in such a way as to allow downward price adjustment if necessary without sacrificing desirable gross margin?

A I am not sure I understand that question.

Q Okay. If they told you they were going to set their price in such a way and they were going to sell the unit at such a price that they could have room enough to lower their price later and still have an acceptable gross margin, would you permit that?

A The question FDA judges is whether the cost that's proposed for the device is supported by the cost that the company will incur in conducting the study or in reducing the device. The issues of competitiveness with other products has no bearing on the cost of the system that FDA will justify. In fact, if these points

are brought up, FDA would probably exclude those parts of the cost from coverage.

Q Which parts?

A The parts that are involved in the competitiveness; that is, the parts that are specifically identified as being — the parts of the cost that are specifically identified as being made to be more competitive or to compete with other products [Veale — page 63] or —

Q You mean they wouldn't want Medtronic to do that?

A That's right. They cannot use that as supporting the cost for the —

Q And if Medtronic did that and if you knew about it, the FDA would object to that conduct; is that correct?

A Not necessarily. The essential issue is whether the product is — whether they are charging enough for the product to cover their cost or not. Typically on a study of this nature, the actual cost involved with each patient or each implant far exceeds the cost that's actually charged.

Q Excuse me. I think you are going beyond my question.

MR. MALLOY: I know Mr. Levin would want him to continue, Your Honor, but I think he has gone beyond my question.

THE COURT: No, I don't think he is. I will permit it.

BY MR. MALLOY:

Q Okay.

A And in most cases, almost any charge can be justified for a device of this nature because of the extremely high cost involved in conducting clinical study.

Q Okay. So in the IDE study, would it be permissible to charge a cost for the unit which would be five times the cost of labor, burden and materials for the product itself?

[Veale — page 64]

A If the — I don't know that you can specifically say that. It is a question of whether the cost of putting the device together, the components and so forth justify. FDA realizes that each one of these devices in a study like this is essentially hand-made. In a study as early as this, devices are basically hand-made.

Q Well, excuse me, but you don't know whether the Medtronic device was hand-made or not.

A I have no idea whether it was or not. What I am saying is FDA's approach to these kind of situations that they recognize these products, the cost involved in per unit and implanting a device like this at this early stage of the clinical investigation is extremely high and they will generally adjust — generally approve almost any reasonable cost.

Q So for example, you are saying that the FDA would approve a cost if the cost of the unit were — let me say it the other way around. If the selling price of the unit were five times the cost of labor, burden and materials, and if you knew that fact, could Medtronic still get approval under 90E and sell its product for five times —

A If they can justify that cost they can.

Q Okay.

A For instance, the research cost that went into developing the device is a legitimate cost to include and charge and typically research, the research that went into a device like [Veale — page 65] this is quite large.

Q And so as long as the research costs weren't used up, you could charge almost anything you wanted for the units during the clinical, so long as you didn't use up the research cost; is that correct?

A As long as you can justify it on the basis of recovering the cost that went into developing the device and the costs that are involved in conducting clinical studies and producing each of the devices that are used in the clinical study.

Q Would it be permissible to use the IDE study to plan the elimination of a competitor?

MR. LEVIN: Objection, Your Honor. There is no foundation for this question.

THE COURT: I will sustain the objection.

MR. MALLOY: Would you hand the witness Exhibit 139.

MR. LEVIN: Your Honor, we have an objection to this exhibit.

THE COURT: Let me take a look at it. Why don't you talk it over between yourselves first.

(Brief pause.)

BY MR. MALLOY:

Q Would it be permitted in terms of your understanding of no commercialization to go out and tout the product under the IDE clinical as making the party who manufactured the IDE product the tachycardia leader of the world? Would that be permitted?

[Veale — page 66]

A The FDA frowns on making claims of safety and effectiveness about a device in advance of the device being approved. It doesn't care if a company promotes itself as making a device or being a leader in a field, so long as they don't make any overt claims about the safety and effectiveness of the device.

Q Would it be permitted to display the unit and demonstrate it at a worldwide cardiology convention to all the potential customers for the unit, even though those customers weren't planned to be investigators?

A It would be permissible to display it as long as the display is clearly labeled that it is an investigational device and that the device isn't available for commercialization.

Q Would it be permitted to do what's called pre-selling to educate the potential customers of the unit to its features and to indicate that this was going to be a device coming down the pike?

A I am not sure what you mean by pre-selling, but if I understand it to mean offering it before it is available, offering it before it is actually available, I think FDA would consider that commercialization.

Q Would it be permissible under an IDE to use the product under the IDE and then to proclaim to all the potential customers, regardless of whether they were going to be involved in the IDE or, to proclaim to them that Medtronic will be the major supplier of implantable defibrillators and that — and [Veale — page 74] that not on any personal experience with implantable defibrillators; correct?

A That's right.

Q And not on any understanding or information about where Medtronic is with respect to its manufacture of the 7215 or further, 7216 units; is that correct?

A That's correct.

Q And Medtronic, as far as the FDA is concerned, can manufacture all the units it wants in the United States so long as the units aren't assembled from top to bottom and then ship them into Canada or some other country without FDA approval; is that correct?

A As long as the — an unapproved device isn't shipped in Interstate Commerce in the United States, that's correct. FDA would consider an assembled device with a packaged for use to be a product that would be shipped in Interstate Commerce that would be subject to FDA's regulations.

Q So as long as they keep it in two parts, they can ship it out, put it together?

A Well, within reasonable constraints, that's the case. The bottom line, if you will, on FDA's regulation of those sort of situations is that the product that's going to be commercialized can't be shipped in Interstate Commerce.

Q And in all your testimony today, you are not appearing here as an expert to say whether or not any patent is infringed?

DAY 13 TRIAL TRANSCRIPT
[page 10]

Lee's deposition, page 96, Your Honor, and we have the very same objection.

MR. JOHNSON: Your Honor, if I may, I would like to read the two questions.

THE COURT: Sure.

MR. JOHNSON: Or three questions that are involved here.

MR. MALLOY: What page?

MR. JOHNSON: This is page 70, and 71.

"How has CPI been harmed, if it has been, by Medtronic's activities with respect to its PCD?

"Answer, I don't know.

"Do you know of any damages at all to CPI as a result of Medtronic's tests concerning its PCD?

"I don't know.

"Do you know of any?

"No, I don't. I don't know.

"Do you know of any sales of CPI devices which have been lost to Medtronic?

"As I stated earlier, the two implantable devices in Canada perhaps have been lost sales in those patients who needed an implantable high energy defibrillator. I do not know that. I do not know the situation involving those two patients who had received this device, if in fact there were two patients in Canada."

DAY 13 TRIAL TESTIMONY OF JON LEE
[page 100]

MR. JOHNSON: Page 96, line 15.

"BY MR. JOHNSON:

Q Do you know of any VENTAK sales which have been lost to sales of Medtronic devices?

You can answer the question.

A Probably the units that were implanted in Canada, Medtronic units implanted in Canada.

Q Do you know whether the physician who implanted units in Canada was authorized to implant VENTAK units?

A I don't know.

Q Do you know whether the conditions of the patients involved in Canada were such that they might have been eligible for implantations of VENTAK devices?

A I just don't know.

Q What information do you have, if any, that indicates to you that the — any implants of Medtronic devices in Canada resulted in lost sales to CPI?

A I am only speculating."

MR. JOHNSON: Do you want your designation at 132?

MR. MALLOY: Yes.

"BY MR. JOHNSON:

Q Is its market share increasing or decreasing in the pacer area?

A It's increasing."

DAY 13 TRIAL TESTIMONY OF
PAUL W. WYLIE
[page 161]

Given these factors, I would expect that Medtronic would open with an offer of about three percent for a license and I would expect that Intec would counter for something much higher than that and there would be back and forth negotiation.

I think the factor that might tip the scale here would be that Medtronic did not have to do their experimentation even for U.S. FDA purposes in the United States. They could do it

outside the country and submit the data from implants outside the country to the FDA to obtain their approval. Medtronic had a plant in the Netherlands and I understand that all of the 7210 devices came from the Netherlands plant, so it might have been an easy enough matter for them to conduct this experimentation outside the United States.

DAY 18 TRIAL STIPULATION
[page 29]

THE COURT: Good morning, ladies and gentlemen. I apologize for the fact we were not ready for you on Thursday, we were not ready for you on Friday and that we have kept you waiting this morning. I hope this will be your last wait.

As I told you before, the evidence is closed, but the parties have agreed that there is one additional bit of information evidence which comes to you in the form of a stipulation and this in effect is one more bit of evidence.

Now, a stipulation is exactly what you think it is. It is an agreement by the parties that facts which are related in the stipulation can be accepted as true without any further proof. This is what the stipulation says. "The parties have agreed that the selling price of Medtronic 7210 device was \$10,000. The parties have also agreed that the selling price of Medtronic's PCD Model 7215 was \$17,000."

**DEPOSITION TRANSCRIPT OF
TERRELL WILLIAMS**
[page 202]

Q Where did you see the memo?

A Where was I?

Q Yes.

A At Medtronic.

Q Where in Medtronic? Were you in your office?

A I don't remember where I was when I saw the memo.

Q Did you receive a copy on your desk?

A I'll take that back. I could have read it at home if I had thrown it in my briefcase.

Q Who wrote the memo?

A I think it was Jack Keimel.

Q Tell me in words or substance what the memo said.

A The memo said we won't now or in the future market release the 7215.

Q Did it give any reasons?

A Let's see, no, I don't think they did.

Q Was it a one-sentence memo?

A No, it was — I think it dealt with other topics, too.

Q Had you ever heard that Mr. Griffin had a different view with respect to whether or not the 7215 would be market released?

[Williams - page 203]

A Oh, I imagine he probably did when they started the project.

Q And what is your understanding of Mr. Griffin's view today?

A His view today is that it won't be market released, that's pretty clear.

Q What do you mean by "market released"?

A That means commercial distribution.

Q Did the memo indicate how many units of the 7215 would be sold at any time?

A I don't recall.

Q Now, you didn't interpret that memo to mean that the Model 7215 wouldn't be sold, did you?

A No, I said market released.

Q All right. It's your understanding that it is Medtronic's full intention to go ahead and sell the Model 7215?

MR. LEVIN: I'll object to that question.

BY MR. MALLOY:

Q Correct?

A What we — we get back a certain amount of reimbursement for devices that we distribute but it is not a commercial venture. It doesn't provide positive cash flow.

Q Well, when you say it doesn't provide

**DEPOSITION TRANSCRIPT OF
LARRY BOWLING
[page 13]**

provided reprints of published articles to people that requested information about the device. But that was the only education, if you want to call that education, that we provided.

Q Are you finished with your answer?

A Yes.

MR. LEVIN: Off the record.

(Whereupon, there was a brief discussion held off the record.)

Q As part of your responsibilities during this time period, or starting in 1984, did you or anyone on your staff bring posters or prototypes or other information regarding the AID-B device to meetings, for example, of the American Heart Association?

A Yes. We had a booth at the American Heart Association which had the things you described in it.

Q Did you have a booth every year at the American Heart Association meeting?

A Yes, we did.

Q Starting in 1984?

A Starting prior to that.

[Bowling — page 14]

Q Did you have booths at any other meetings attended by cardiologists or physicians?

A We had a single booth. It was a very small limited booth which basically showed the device and where it was implanted. We passed out literature. There was a sign in the booth that said device in clinical investigation, not for sale, which is required by the FDA. We attended, initially, two meetings.

Q Per year?

A Per year, the American College of Cardiology, and the American Heart Association. Later we started going to the North American Society of Pacing and Electrophysiology convention.

Q At these meetings, were physicians and cardiologists who had not yet received approval from the FDA to participate in the clinical trials eligible to come to your booth and receive information about the AID or AID-B devices?

A Yes.

Q Was it your desire that they come to the booth to use that information?

A Yes.

[Bowling - page 15]

Q Was it the intention of setting up these booths at these meetings to develop interest in not then participating cardiologists or physicians who would then try to or who would then later become part of the clinical trials?

MR. SHIFLEY: Objection. Leading.

A The primary purpose of the booth was information, to disseminate information about the automatic implantable defibrillator. Our hope was that we would develop a certain amount of interest in the device so that once it was approved by the FDA we could begin to market it and we would have a reservoir of physicians' names that we could then contact.

Q Is it correct then that you do not consider setting up a booth at an AHA meeting, ACC meeting or a meeting of the Society of Pacing and Electrophysiologists to be marketing?

MR. SHIFLEY: Objection. Leading, beyond personal knowledge, calling for an opinion as opposed to factual testimony, asking the man for expertise about knowledge he doesn't have. Go ahead and answer.

[Bowling - page 16]

A A booth can have many different purposes at a meeting. It can provide information. It can be there for marketing purposes, or you can conduct surveys, many, many different reasons. Because the FDA strictly prohibits a company from marketing a product until it is approved, then we could not do that. So our purpose was information. We disseminated clinical papers that were published and answered questions regarding the status of the investigation.

Q Is it correct then that you considered the dissemination of that information and the display of the devices at these booths during the time, that they were in clinical trials not to be marketing?

A In my definition of marketing, yes.

Q Your definition of marketing is what?

A We were not soliciting to sell the device or to expand sales of the device, because we couldn't.

Q Was Intec receiving revenue for its providing of the devices to implantation centers during the clinical trials?

A Yes.

[Bowling - page 17]

Q Was that sales of the devices?

MR. SHIFLEY: Same objection as past.

A You know, again, we were able to recover a portion of our cost for manufacturing and the training and all of the other things that were involved in having that device available for

implant. We billed the customer for that. We did not recover the full cost of the device during that period of time.

Q Are you finished with your answer?

A Yes.

Q Do you know whether or not Intec was losing money in 1984?

A Yes, I do.

Q Was it?

A Yes.

Q Were part of your responsibilities at Intec starting in 1984 to expand the scope of the clinical trials in order to bring more revenue into Intec?

MR. SHIFLEY: Objection. Leading, asked and answered.

[Bowling - page 90]

University of Indiana, [sic] an Intec device could not be implanted?

A At the University of Indiana. [sic] They could have been implanted at others, as was the case of several patients of his.

Q Do you know of any particular implantation of a Medtronic device during the time you were at Intec which implantation deprived Intec of having its own device implanted in that patient?

A I don't know of any.

MR. LEVIN: Let's take a short break.

(Whereupon, there was a brief recess taken.)

Q Mr. Bowling, did there come a time when you became aware that Intec Systems had filed a lawsuit against Medtronic?

A Yes.

Q For alleged infringement of two Mirowski patents under which Intec was licensed?

A Yes.

Q Did you take part in the consideration within Intec of whether or not to file that lawsuit?

DEPOSITION TRANSCRIPT OF JON LEE
[page 96]

defibrillation thresholds by orthogonal, time-separated shocks?

A I don't remember, probably because I don't quite understand it.

MR. SHIFLEY: You are not alone.

BY MR. JOHNSON:

Q Has CPI been financially damaged in any respect by Medtronic's alleged infringement in this lawsuit?

A Not that I am aware of.

MR. SHIFLEY: Let me state for the record I don't expect this man to be an expert as to damage. He is here as to marketing. Again its personal opinion and not a 30(b)(6) opinion.

BY MR. JOHNSON:

Q Do you know any Ventak sales which have been lost to sales of Medtronic devices?

MR. SHIFLEY: Again, this is not a 30(b)(6) witness on this topic. You are getting personal opinion.

BY MR. JOHNSON:

Q You can answer the question?

A Probably the units that were implanted in Canada. Medtronic units implanted in Canada.

Q Do you know whether the physician who implanted units in Canada was authorized to implant Ventak [Lee — page 97] units?

MR. SHIFLEY: Do you know if he needed authorization to do so. As a preliminary go ahead and answer.

THE WITNESS: I don't know.

BY MR. JOHNSON:

Q Do you know whether the conditions of the patients involved in Canada were such that they might have been eligible for implantation of Ventak devices?

A I just don't know.

Q What information do you have, if any, that indicates to you that the — any implants of Medtronic devices in Canada resulted in lost sales to CPI?

A I am only speculating.

Q You have no firsthand knowledge of information?

A No.

Q From time to time did CPI present information concerning its Ventak devices at regular professional society meetings?

A Yes.

Q Does it encourage its investigators to present information concerning its — their clinical experience with Ventak devices?

A Yes.

DEPOSITION TRANSCRIPT OF
BRUCE RAYKOWSKI
[page 70]

If that's — I don't know that.

Q What is the current market share of CPI in the cardi-overter defibrillator area?

MR. MALLOY: I'm going to object to the term market if you're using it in an economic sense, Counsel, or a legal sense. But to the limited lay extent the witness has, he may answer, if he knows.

A I would assume — We are the only company today manufacturing an AICD. If it's the market that you're referring to, I would assume that we have 100 percent.

BY MR. JOHNSON:

Q How has CPI been harmed, if it has been, by Medtronic's activities with respect to it PCD?

MR. MALLOY: Don't speculate or guess. He is asking you what of your own knowledge.

A I do not know.

BY MR. JOHNSON:

Q Do you know of any damage at all to CPI as a result of Medtronic's tests concerning its PCD?

A I don't know.

[Raykowski — page 71]

Q You don't know of any?

A No, I don't.

MR. MALLOY: Counsel, I think the question is objectionable, because the witness has already testified that he has a limited knowledge about the device, itself.

A I don't know.

BY MR. JOHNSON:

Q Do you know of any sales of CPI devices which have been lost to Medtronic?

A As stated earlier, the two implantable devices in Canada perhaps have been lost sales, if those patients needed an implantable high energy defibrillator. I do not know that. I do not know the situation involving those two patients that received this device, if in fact there were two patients, in Canada.

Q Are you speculating?

A I don't know.

Q You don't know whether you are speculating?

MR. MALLOY: Counsel, you're realling [sic] arguing with the witness.

MR. JOHNSON: I'm not arguing. I'm just asking whether he has factual

PX-54

MEDTRONIC

Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis MN 55432 USA
Telephone (612) 574-4000
Cable Medtronic Telex 29-0598

April 25, 1986

Center for Devices and Radiological Health
Food and Drug Administration
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

RE: Supplement to IDE Number G830084

Termination of the Medtronic Model 7210 Clinical Study

Gentlemen:

The purpose of this letter is to inform you of our intention to terminate the Medtronic® Model 7210 Multiprogrammable Tachycardia Control System clinical study in accordance with Part 812.150(b) (7). A letter to the Model 7210 investigators will be sent shortly. A Final Report will be submitted to FDA, all reviewing IRBs and participating investigators in about one month.

Medtronic considers the contents of the IDE submission to be confidential commercial or trade secret information and requests it be given full protection under the law. This letter is submitted in triplicate in accordance with the IDE Regulation.

If further information is required please contact the undersigned.

Sincerely,

MEDTRONIC, INC.

/s/ TIMOTHY J. JOHNSON
Timothy J. Johnson
Product Regulation Manager
(612) 574-3482

CVS

PX-91

MEDTRONIC

INTER-OFFICE MEMO

TO:	Alain Rigal	cc:	Ed Duffin
FROM:	T.V. Rao		Bill Erickson
DATE:	December 31, 1986		Jake Gjoraas
SUBJECT:	MODEL 7215 PCD™—PRICING		Jim Grams
			Bobby Griffin
			Tim Johnson
			Mike Kallok
			Jack Keimel
			Gerard Planchon
			John Roberts
			Marty Rossing

Model 7215 PCD™—Medtronic pacer—cardioverter-defibrillator is a first of its kind for Medtronic. It represents major breakthroughs for Medtronic in the field of tachyarrhythmia implantable devices. It also represents major breakthroughs in technology available to physicians to manage their tachyarrhythmia patients. The following are some of the considerations reviewed in arriving at a price for the above system.

- Relative to other Medtronic products, PCD™ is highly sophisticated and extremely complex and demands a premium price compared to the highest priced brady product.
- Relative to the AICD™ (\$10,500) implantable pulse generator, PCD™ has
 - Lower maximum deliverable energy
 - Higher technology and sophistication
 - Smaller in size where size matters
 - A market that is dying for it (pun intended)
- The demand for the PCD™ system is extremely high today as evidenced by
 - Constant pressure from EPs to be investigators
 - Customer pull
 - The insatiable demand created by Intec

- The reimbursement scenario is as follows:
 - Approximately \$22,000 for first implant including the procedure (DRG 104).
 - Average cost of the procedure is \$35,000 according to ACC letter to HCFA.
 - Replacement DRG 117 pays only \$8,000.
- The PCD™ system
 - Safety and efficacy remains to be proven through clinical studies.
 - Energy level may limit its indications.
 - Has sophisticated pacing therapies that may avert VF.

Alain Rigal
December 31, 1986
Page 2

- Other competitive, comparable systems include:
 - AICD (CPI)—Defib only—approved.
 - Guardian (Telectronics)—Defib + brady.
 - ?? (Intermedics)—Potentially sophisticated.
 - ?? (Ventritech)—Presumed sophisticated.
- The PCD™ system pricing should
 - allow head room for device improvements
 - allow competitiveness with existing AICD
 - be marginally premium priced compared to AICD
 - prevent undue price visibility
 - limit head room for less sophisticated devices
 - allow downward price adjustment if necessary without sacrificing desirable gross margin
 - encourage use of system purchase concept
 - not discourage prophylactic patch implant

Based on the above considerations, the following pricing structure has been established.

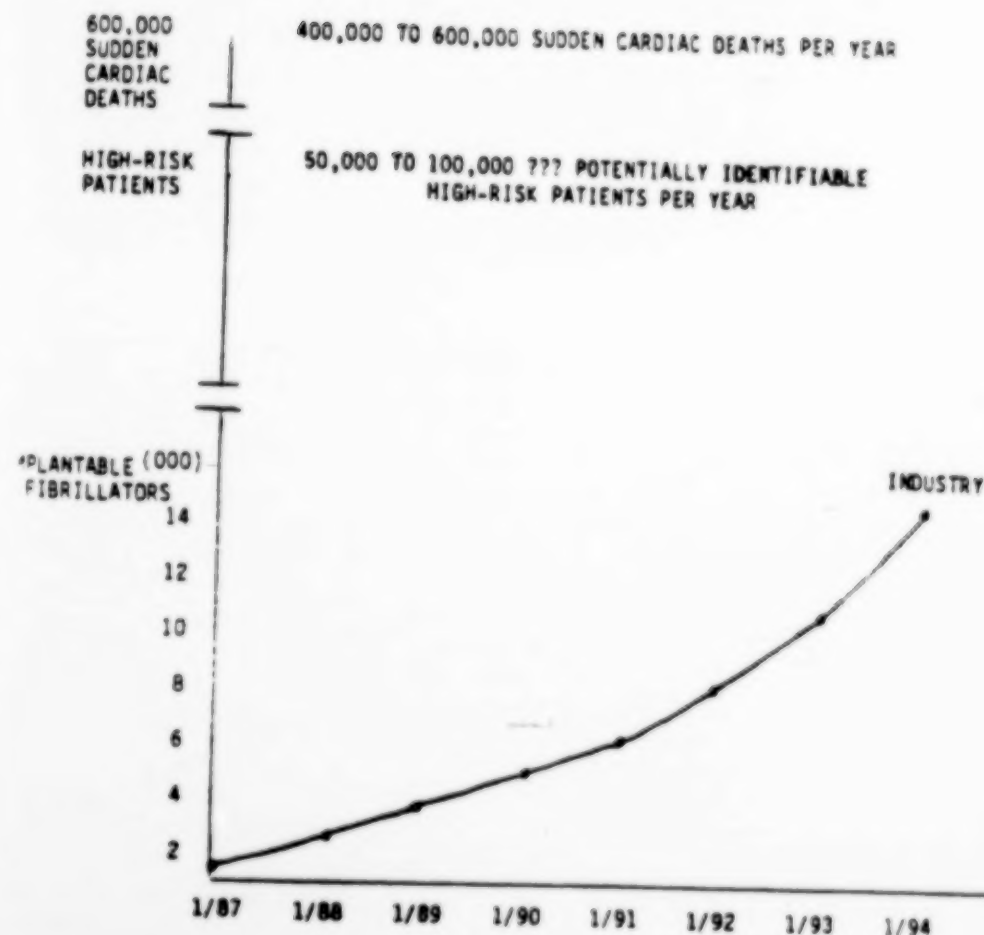
Model 7215 PCD™ Implantable Pulse Generator	\$12,500
(3) Patch leads (Models 6888, 89 or 90) at \$950 ea	2,850
(1) 6917 screw-in epicardial lead	600
(1) 6886 adaptor	250
Total	\$16,200

The PCD™ system price consisting of the above components would be \$15,500 if they are purchased as a system resulting in a \$700 discount.

MP12/4293D

PX-139

THE IMPLANTABLE DEFIBRILLATOR MARKET & U.S. MARKET POTENTIAL



ASSUMPTIONS: EARLY '90s

- Diagnostic improvements (E.P., CAD, Ejec. Frac.)
- General acceptance of E.P. by C.D.
- Grow acceptance of screening criteria
- Non-thorocotomy implant

PCD UNIT/REVENUE PROJECTION

			PAST	\$15,000
		(000)	(000)	(000)
	Units	Revenue	Revenue Cum.	Costs Cum.
FY'88 (7215)	60	\$ 600	\$ 600	\$18,000
FY'89 (7216)	240	2,400	3,000	18,700
FY'90	800	8,400	11,000	21,000
FY'91	3,200	36,400	47,800	21,800
FY'92	4,500	44,600	92,000	22,600

AssumptionsPrice

- U.S. \$12,000
- INTERNATIONAL \$8,000

UNIT SPLIT DURING CLINICAL

- U.S. 50%
- INTERNATIONAL 50%

UNIT SPLIT MARKET RELEASE

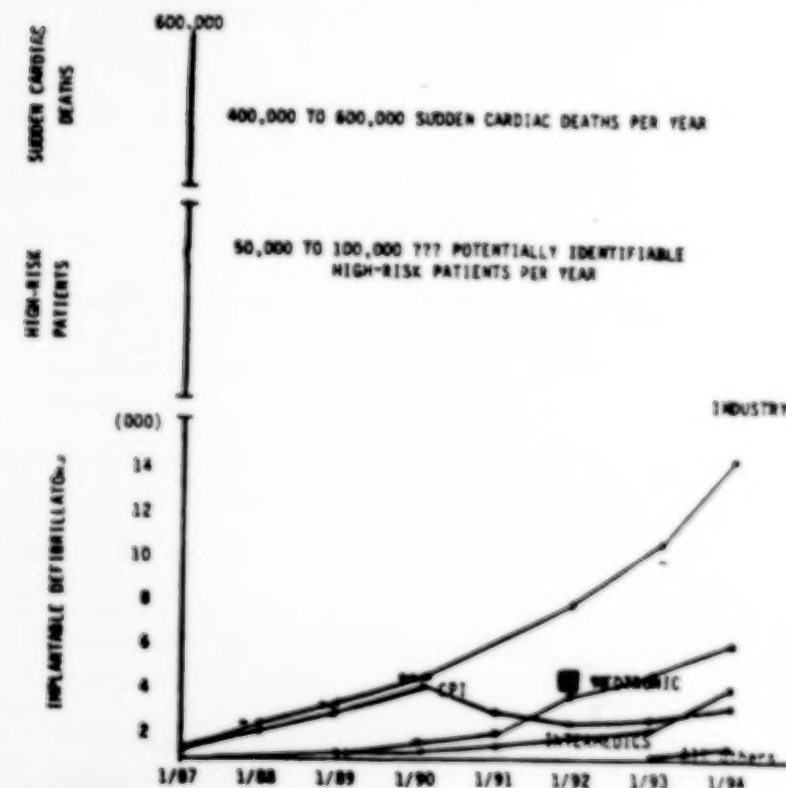
- U.S. 75%
- INTERNATIONAL 25%

COST: VARIABLE/SYSTEM = \$3,000/SYSTEM
(INITIALLY = \$3,600/SYSTEM)

HISTORICAL INVESTMENT

AID	\$ 1.0 MIL
Zsx	3.3 MIL
PCD ₁₅	7.7 MIL
MARKETING	3.0 MIL
TOTAL PAST	\$ 15.0 MIL

THE IMPLANTABLE DEFIBRILLATOR MARKET & U.S. MARKET POTENTIAL

ASSUMPTIONSCPI

- * Supply problems
- ** Ventak P released
- *** Ventrak PRX released

Telectronic

Not a factor

Ventritex

Is acquired by Medtronic, however if acquired by Siemens-Pacesetter they will command 10-20 share by 1992.

Medtronic

Achieves current plan, including International release of 7216 summer 1989. U.S. release early 1990 with a transvenous lead during 1990.

Intermedics

Starts clinical of a "PCD" device during 1983 and achieves approval 30 months later.

PROJECTED TACHY UNITS/REVENUES

	<u>FY'88</u>	<u>FY'89</u>	<u>FY'90</u>	<u>FY'91</u>	<u>FY'92</u>
5326/28 UNITS	84	50	25	20	20
\$ (000)	\$ 732	\$ 435	\$ 217	\$ 174	\$ 174
7008 UNITS	12	20	6	—	—
\$ (000)	\$ 72	\$ 120	\$ 36	\$ —	\$ —
5998 UNITS	12	12	12	—	—
\$ (000)	\$ 24	\$ 30	\$ 30	\$ —	\$ —
PCD UNITS	57	240	800	3,200	4,500
(7215/7216)					
\$ (000)	\$ 600	\$ 2,400	\$ 8,400	\$ 36,400	\$ 44,600
MESA UNITS	5	40	50	60	60
\$ (000)	\$ 100	\$ 1,000	\$ 1,250	\$ 1,500	\$ 1,500
EP MEM MOD					
UNITS	—	300	100	50	50
\$ (000)	—	?	?	?	?
<hr/>					
ANNUAL REVENUE					
\$ (000)	\$ 1,528	\$ 3,985	\$ 9,933	\$ 38,074	\$ 46,274

PX-142

MEMORANDUM

TO: Medtronic Jerusalem Attendees
 FROM: Mike Toffoli
 DATE: June 3, 1987
 SUBJECT: TACHYCARDIA MANAGEMENT SYSTEMS

POSITIONING STATEMENT FOR JERUSALEM:

- A. Medtronic will be the major supplier of implantable defibrillators, and external E.P. stimulators . . . "Doctor your medium/long range partner in tachy control devices is Medtronic."
- B. Medtronic will be a key contributor in advancing the science relevant to tachycardia detection and therapy.

STRATEGY:

- A. Expedite the PCD development and clinical evaluation achieving a releaseable (International) 30 joule system by summer 1989.
- B. Develop a thorough understanding of electrophysiology and design/supply instrumentation that improves the electrophysiologists productivity, accuracy, etc.
- C. Short term, leverage education programs and research projects that will build credibility and rep relationships critical to future success.

TACTICS:

PCD (pacer-cardioverter-defibrillator) clinical will begin in June 1987 (Canada). This 15 joule output device is the first to offer "staged electrical therapy." It is very programmable, providing the capability to tailor independent VT/VF detection criteria . . . the powerful VT detection algorithm, for example, can employ up to 4 criteria to define and qualify a VT! A variety of therapies can be tailored for VT including: premature stimulation, adaptive burst pacing, decremental overdrive pacing

and cardioversion. VF can be treated with up to 4 defibrillation shocks (programmable energy level).

This device, the 7215, is very sophisticated and is already being chronically evaluated in dogs. In humans, defibrillation thresholds of 10 to 25 joules are not infrequent, therefore, a 30 joule PCD is being expedited and will be introduced into the PCD clinical study in less than one year. It is this 30 joule PCD (7216) that we plan to release (International) during the summer of 1989.

Obviously, it is desirable to achieve a transvenous defibrillation system (or at least a "non-thoracotomy system). Medtronic's work on such a system began in the early 1980's with the implantable cardioverter and the 6880 leads. That lead work plus more recent efforts both in Minneapolis and at IRSC will result in transvenous and transvenous/subcutaneous patch lead systems that will be under clinical evaluation before the release of the 7216 PCD.

MESA, The Medtronic Electrophysiological System Analyzer, is another example of our commitment to attaining a leadership position as a supplier of stimulation equipment to the electrophysiologists.

This powerful and easy to operate system utilizes an IBM-AT coupled with a Medtronic atrial/ventricular stimulation interface, an eight channel signal acquisition interface, a unique keyboard and a powerful software program.

The MESA will avail the user automatic standard EP protocols, including:

- Sinoatrial conduction time
- Sinus node recovery time
- Atrial/ventricular effective refractory periods
- Atrial/ventricular arrhythmias induction
- A-V stimulation

and provide back-up therapies; including:

- Burst therapy (Fixed rate or rate adaptive), and
- SS1 pacing

MESA utilized four of the signal acquisition channels (high right atrium, HIS bundle electrogram, right ventricular apex and the surface ECG lead with earliest QRS) and a very reliable automatic cardiac event detection system to automatically record and analyze and generate EP reports. MESA significantly automates a currently labor/time intensive EP study.

Bottom line during the World Pacing Symposium we have to acknowledge that CPI now is the market leader in implantable defibrillators . . . they have 100% share and on that measure, no place to go but down! (At one time CPI had 100% of the lithium pacemaker market too . . . but . . .).

However, we must exude confidence and commitment that Medtronic will bring to the market tachy control systems that will certainly earn the market leadership position by the time we reconvene at the next World Pacing Symposium!

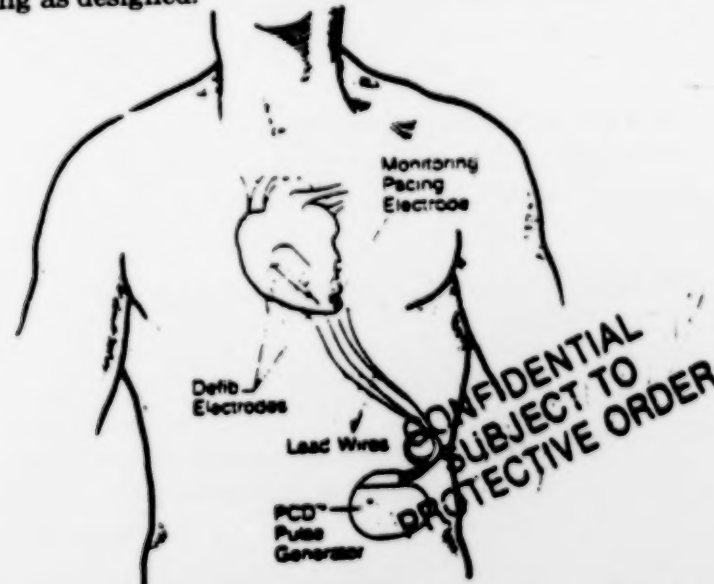
RAPID PULSE MEDTRONIC

JULY 2, 1987

First PCD Implant Launches Clinical Trials

The first implant of Medtronic's PCD—Pacer-Cardioverter-Defibrillator—occurred June 18 at the University of Western Ontario in London, Ontario. Surgeon Gerard Guiraudon and cardiac electrophysiologist George Klein implanted the PCD in a 45-year-old male who suffers from a form of tachyarrhythmia: recurrent ventricular tachycardia that deteriorates to ventricular fibrillation.

According to Fellow Mike Kallok, a research scientist on the project, the patient is doing well and, since the implant, has experienced one spontaneous arrhythmia which the PCD terminated successfully. "The implant went very well," says Kallok. "There were no problems during surgery and the device is performing as designed."



The PCD consists of a pulse generator containing the batteries, microprocessor, and related circuitry. It weighs about six ounces and measures about 3¼ inches long, 3 inches wide, and ¼ inch thick.

Four leads carry electrical signals between the pulse generator and the heart. One standard pacing electrode senses the heart's activity and paces the heart. The other three patch electrodes are sewn onto the outside of the heart and deliver shocks from the pulse generator to the heart. Each patch electrode measures approximately 2 inches by 3 inches.

Pacing Business Unit vice president Bobby Griffin says this first implant is significant for Medtronic. "We're now the technological leaders in the tachy arena. Despite stiff competition, it's our task to advance that position."

Treating Tachy

There are two types of tachyarrhythmias: atrial and ventricular. Atrial tachyarrhythmias currently may be controlled by drugs or pacemakers such as the Symbios 7008, now in clinical trials.

Ventricular tachyarrhythmias, on the other hand, can be very severe.

- Ventricular tachycardias (VT) cause the ventricles to beat so rapidly that they don't have time to fill with blood, thus drastically reducing cardiac output.
- Frequently, VT leads to ventricular fibrillation (VF), which results in a quivering heart muscle that is unable to pump any blood, often resulting in sudden death.

Medtronic's PCD is designed to monitor the heart rate continually and detect and treat these life-threatening episodes.

How PCD Works

The PCD detects episodes of ventricular tachycardia by measuring the time interval between each heartbeat. When the interval becomes too short, the device is designed to try to correct the rate with electrical therapies which become stronger as the episode continues.

The device combines pacing therapies, the 'P' in PCD, and low energy shocks called cardioversion, the 'C', to end the episode. If the device detects ventricular fibrillation, it will deliver higher energy shocks called defibrillation, the 'D' in PCD.

The device delivers only as many therapies as needed to stop a tachyarrhythmia. A series of VT or VF therapies can range from one imperceptible pacing sequence to up to four shocks.

The PCD's memory stores crucial facts about the patient's heart rate, device operation, and therapies delivered. Physicians may retrieve this information during checkups.

Patient Benefits

Each year in the U.S. alone, an estimated 400,000 cases of sudden cardiac death probably begin with ventricular tachyarrhythmias.

Drugs and surgery are the usual treatments for VT and VF, but for many patients surgery may not be an option and drugs may be ineffective or cause adverse side effects.

Because the PCD is designed to treat tachycardias promptly, patients may have shorter episodes of tachycardia and may avoid fibrillation. If fibrillation occurs, prompt termination may avoid later complications.

Compared to the shocks delivered with external defibrillation paddles by emergency medical teams, each PCD defibrillation shock is delivered at 25 times less energy. This avoids a burning sensation to the patient's skin associated with the external paddles.

Delivery What The Doctor Ordered

Medtronic's current tachy venture started with a complete analysis of customer requirements by marketing, engineering, and research.

"The PCD has been designed to fulfill our customer's requirements," says director of tachyarrhythmia marketing Mike Toffoli. "Electrophysiologists have asked for a system that 'does it all.' They want a device capable of bradycardia pacing, tachycardia overdrive pacing, cardioversion, and defibrillation. The PCD does all those things. It is a significant achievement for Medtronic.

"The business implications for the company are many," continues Toffoli. "Sudden death is a significant problem begging for a solution and the PCD device is the desired solution."

Status Of Clinical Trials

This first implant marks the start of the device's clinical trials, a crucial part of the product approval process. More clinical implants are scheduled in Canada. Clinical trials will begin in the U.S. when the Food and Drug Administration approves the PCD investigational device exemption. Approval is expected sometime this summer.

Tachyarrhythmia Management Bulletin

Bulletin #3, July 10, 1987

MEDTRONIC TACHYARRHYTHMIA MANAGEMENT OBJECTIVES & STRATEGIES

OVERALL OBJECTIVE: to be recognized as the research, technology, product and market leader in tachyarrhythmia control devices.

BUSINESS

Strategy: Focus on ventricular tachycardia and ventricular fibrillation segment. (That's where the medical challenges, volume and profits are.)

MARKET DEVELOPMENT

Strategy: Begin to establish a relationship with electrophysiologists now by marketing diagnostic stimulators and by establishing a leadership role in market education regarding tachyarrhythmia diagnosis and therapy.

Tactics FY '88

- Sell currently available products (Models 5328 and 5998 Stimulators); and introduce the EP MemoryMod this year and the MESA System next summer.
- Leverage market development and market education through courses such as "How to Approach Complex Arrhythmias (September, 1987 and February, 1988).
- Inform national sales force about product/program status and rationale with regular tachyarrhythmia bulletins starting in July, 1987.

- Increase sales force confidence with EP terminology and discipline so consultative relationships with EPs are possible — soon!

PRODUCT DEVELOPMENT

Strategy: Rapidly develop diagnostic stimulators and an implantable defibrillator that meets market requirements and norms (30 joule output, bipolar sensing), then advance science of VT/VF control. (Get in the game, then win the cup.) Leverage our powerful global distribution system to achieve a dominant market share position.

Tactics FY '88

- Begin clinical evaluation of the 15 joule Model 7215 PCD device and supporting instrumentation in June, 1987. This clinical base will be "applied" to the FDA submission for market approval of the 30-joule Model 7216 PCD to help expedite approval.
- Begin clinical evaluation of the 30 joule Model 7216 PCD May, 1988.
- Introduce the Model 9780 EP Memory Mod during the fourth quarter, FY 1988. Target promotional efforts at EPs with pacing practices.
- Introduce Model 2390 MESA (Medtronic Electrophysiological Systems Analyzer) Spring/Summer, 1988, aiming promotions at EP centers.

RESEARCH

Strategy: Gain a better understanding of EP mechanisms, sensing, detection, therapeutic requirements and lead configurations. Leverage relationships with key research centers and opinion leaders to achieve and sustain perceived product and technical market superiority.

Tactic FY '88

Continue research to advance detection and treatment of tachyarrhythmias with several funded projects.

PX-579

Medtronic

INTER-OFFICE MEMO

TO: Dwight Warkentin
 FROM: Mike Toffoli
 DATE: 8 April 1987
 SUBJECT: Tachy Objectives, etc.

Attached is a brief outline of objectives, strategies, and tactics as I see them.

Position for Jerusalem should be: Medtronic is making major strides toward a future leadership role in tachyarrhythmia management on several fronts as represented by our first clinical implant of PCD in June, 1987. We should indicate that clinical is beginning on a "staged electrical therapy" device. This early clinical device will have extensive programmability, telemetry, detection schemes, and three levels of therapy including: 1) low energy burst, 2) synchronized cardioversion, and 3) defibrillation up to 15 joules. We should acknowledge tht 15 joules will not be adequate in all patients and a 30 joule device will follow the initial PCD into clinical in less than 1 year. The Instrument support system around the PCD implantable systems is very strong and will include a "Prescription Formulator", programmer, and specialized follow-up equipment.

Additionally, the EP Mem Mod and the MESA will give us a very strong presence in the diagnostic end of the Electrophysiology business.

/s/ M. TOFFOLI

Tachyarrhythmia Management Systems

Mike Toffoli
 8 April, 1987

Objectives:

Be the recognized technology, product and market leader in tachycardia control devices by 1990.

Strategy:

- Focus on the VT/VF segment.
- Enter the market ASAP with a system that will satisfactorily treat ventricular arrhythmias (fulfilling market norms), and leveraging our powerful global distribution system to achieve a dominant market share. (Norms . . . Bipolar Sensing, 30 joule output ect.)
- Gain a superior understanding of the electrophysiological mechanisms and the required sensing, detection, therapeutic, and lead configuration/tissue interface requirements to achieve and sustain superiority.
- Rapidly develop product that meets obvious market requirements (and norms) . . . then advance the science of VT/VF control.
- Establish a relationship with electrophysiologists now through the marketing of diagnostic stimulators and establishing a leadership role in market education regarding tachyarrhythmia diagnosis and control.

Tactics FY'88

- "Harvest" the 5998 and 7008 system eg., continue to sell but without further business investments.
- Sustain sales levels of the 5326/28 EP stimulators with low level investment in sales force/customer awareness.
- Introduce the 9780 EP Mem Mod in January 1988 with promotional efforts targeted at EPs/cardiologists with pacing practices/influences.

- Introduce MESA electrophysiological systems analyzer in January 1988 with promotional efforts targeted at EP centers. (See the attachment for a brief description of MESA.)
- Began clinical evaluation of the implantable PCD system and related instrumentation in June, 1987.
- Expedite development of the 7216 30 joule PCD system and phase the 7216 into the PCD clinical evaluation by May of 1988.
- Continue and intensify market development/education activities through courses such as "How To Approach Complex Arrhythmias", etc. Create a presence through education where we lack hardware. (Sept. 1987 & Feb. 1988)
- Continue research in those areas likely to advance the detection and treatment of tachyarrhythmias (several projects are in process).
- Better inform the distribution system on product/program status, and rational. First Tachyarrhythmia management bulletin to be published July 1987.

PRODUCTS to be displayed in Jerusalem.

The PCD system:

- * 7215 pulse generator
- * Implantable Lead System
- * 9710 Programmer

The 5328 Stimulator

PRODUCT DESCRIPTIONS to be presented
(3 ring binder)

- * MESA
- * E P Memory Mod.

EDUCATIONAL COURSES to be offered

"How to approach complex arrhythmias."

Medtronic

PX-646

INTER-OFFICE MEMO

TO: George Heenan
FROM: Bill Engle/Jerry McCauley
DATE: December 29, 1977
SUBJECT: AUTOMATIC IMPLANTABLE
DEFIBRILLATOR

[p. 5342]

Enclosed please find the rough draft of the automatic implantable defibrillator (AID) venture analysis. Most of the material is in the final form, although the financial analysis is in rough draft form and the program plan and budget are not yet completed. These will be finalized by our January 4 meeting.

We would like to make the following recommendations, assuming that the financial projections in the AID report meet the Corporate criteria for new products:

- 1) Dr. Mirowski appears to be in a position of controlling all relevant patents relating to AID technology.
 - a) Discussions with Mirowski/Medrad should be undertaken to determine options available to Medtronic.
 - b) Begin negotiating appropriate agreements.
- 2) Negotiate with Purdue University on minimal funding necessary to maintain their involvement until a positive or negative indication of willingness to negotiate is obtained from Mirowski/Medrad.
 - a) We suggest that 4-6 weeks time frame is reasonable to determine that an equitable position for Medtronic can be worked out.

- b) Suggest that funding for Purdue to begin animal studies (4-6 dogs) be approved at an approximate cost of \$7,000.
- 3) Obtain a legal opinion of the AID patents internally or from a consultant.
- 4) Initiate the minimum internal activities necessary to:
 - a) Start battery study.
 - b) Design circuit breadboards.
 Estimated cost not to exceed \$8-10K over the six weeks.
- 5) All work on AID program should cease if negotiations are not satisfactorily resolved.

[p. 5363]

V. PROBLEM AREAS/RISKS

A. PATENTS

Dr. Mirowski has been issued several patents in the area of implantable defibrillation. We also know of at least one patent that is pending. Mirowski holds a *very basic* patent on automatic implantable defibrillators. After consultation with our Law Department, it appears it may be impossible to develop an AID without infringing on his patent. It is possible that we could fight his patent and the courts would find the patent invalid, but that is a very costly and very risky alternative.

A preferred approach would be to obtain a license under his patents. To the best of our knowledge, Mirowski has granted Medrad, Inc. an exclusive license to his patents. If the AID appears to be a worthwhile venture to Medtronic, Medrad and Mirowski may be receptive to a fair business proposal. Under our previous agreement with Mirowski we agreed to pay royalties of 4% on external sales and 3% on implantable sales. (We would probably have to increase royalties somewhat.) In addition to the basic patent,

Mirowski has applied for a patent covering the technique for sensing mechanical activity described elsewhere in the report.

On the positive side, Medtronic has or will receive several relevant patents. Rollin Denniston and Tom Davis, both former employees, assigned a patent to Medtronic that deals with sensing more than one parameter for the detection of fibrillation. The status of this patent is somewhat confused. Medtronic has agreed that Mirowski should be named as co-inventor. However, it is not clear whether or not Mirowski will receive a license to practice that invention.

Since Mirowski has applied for a patent for mechanical sensing, why isn't he developing it? We only know that he isn't publishing or discussing that technique. The device he is testing may actually use the mechanical sensing technique. Since he is waiting for Medtronic to list him as an inventor on Denniston's dual sensing patent, Mirowski may not want to tip his hat that he would be needing that dual sensing patent.

A patent may be issued to Medtronic on a technique developed by Bill Engle and Dennis Hepp for inhibition by the patient of false positive trigger signals. This is an invention [p. 5364] that helps further reduce the possibility of false discharge. The patient is alerted by a beeper or by skin stimulation if the AID has determined that fibrillation is present. The patient can then place a magnet over the AID to inhibit the unit from discharging. The patient would lose consciousness within 15 seconds and would no longer inhibit the AID if he is in fibrillation. If the patient retains consciousness he is not fibrillating and can continue to inhibit the AID. This concept adds another source of reliability.

Bill Engle has disclosed another invention which enables noninvasively determining if the AID has been discharged. This will be useful if a patient dies to determine if the AID attempted defibrillation.

Although Medtronic is not in a powerful bargaining position from a patent standpoint with Mirowski and Medrad, we do have at least one patent which may be of interest to them, as well as two other possibilities. Medtronic does have substantial bargaining power from the standpoint of our marketing/technical/manufacturing and distribution capabilities. Medrad/Mirowski must be made aware of these factors in our negotiations.

PX-1404

MODEL 7215 INVESTIGATIONAL PLAN

[Vol. 4, p. 1]

A. STUDY PURPOSE

1. Name and Intended Use of System

The Model 7215 PCD (Pacer-Cardioverter-Defibrillator) is an implantable, multiprogrammable, automatic tachyarrhythmia control device designed to detect and treat episodes of ventricular tachycardia (VT) and ventricular fibrillation (VF). Cardioversion and defibrillation pulses are delivered via a three-electrode system consisting of a combination of epicardial patch electrodes (Models 6891 and 6892). Pacing therapies, both bradycardia (VVI) and tachycardia, and sensing will be accomplished using a bipolar electrode configuration consisting of a standard, commercially-available myocardial pacing electrode and one (1) of the epicardial patch electrodes. Programming and interrogation of the Model 7215 will be performed using the Model 9785 Memory Mod software cartridge in conjunction with the Model 9710 programmer.

Criteria for detection of episodes of ventricular tachycardia are independent of detection criteria for ventricular fibrillation. Up to four (4) independently programmable VT therapies may be chosen and automatically delivered from among two (2) overdrive pacing modes, burst and ramp, and cardioversion. Likewise, up to four (4) programmable VF therapies, all defibrillation pulses, may be automatically delivered after VF detection by the Model

7215. Pacing, cardioversion, and defibrillation therapies may also be delivered manually by the physician via the programmer.

The PCD system is intended for use in patients at risk of sudden cardiac death due to ventricular tachyarrhythmias which have been shown to be terminated reliably and, in the case of VF, terminated at an energy level below the maximum output energy of the Model 7215. Patients will either have survived a previous cardiac arrest associated with ventricular tachyarrhythmia and not associated with a recent myocardial infarction or have recurrent, sustained ventricular tachyarrhythmias despite acceptable drug therapy.

Experience with intracavitary cardioversion/defibrillation using a single pulse has been previously reported (Medtronic IDE for Intracavitary Cardioversion #G820095). Subsequent studies suggested, using a three-electrode system to deliver two (2) defibrillation pulses over two (2) separate pathways in a sequential fashion, that defibrillation could be accomplished with lower voltage and energy than that required for a single pulse delivered across a single pathway.

[Vol. 4, p. 2]

The proposed study within this protocol examines this concept of sequential pulse cardioversion/defibrillation as well as pacing therapies for VT and algorithms for the automatic detection of VT and VF. This study builds on the previous animal and acute human studies on sequential pulse cardioversion/defibrillation of Bourland, Jones, Klein, Kallok, and Zipes; evaluation of decremental overdrive pacing techniques by Charos, Haffajee, and Den Dulk; and studies on tachyarrhythmia detection algorithms by Bardy and Olson. The current study will examine the application of these concepts using a totally implantable system.

2. Study Objectives

This study is designed to evaluate the operation, safety, and effectiveness of the design concepts used in the Model

7215 PCD tachyarrhythmia control device and its associated lead system in detecting and treating episodes of ventricular tachycardia and ventricular fibrillation, emphasizing sequential pulse defibrillation for treatment of VF.

This clinical investigation will consist of a single phase that will require strict patient selection criteria, and careful pre- and post-implant evaluation to ensure maximum patient safety and optimal device performance.

The data will be reviewed by the Clinical Study Monitor, by the Study Medical Consultants and/or all investigators and the Study Research Advisor, Michael Kallok, Ph.D. Reviews will be conducted to determine if there are any significant safety or efficacy issues identified during the evaluation of the Model 7215.

Objectives for the study are:

- to research the design concepts used in the Model 7215 tachyarrhythmia control device and its associated lead system in detecting and treating episodes of ventricular tachycardia and ventricular fibrillation;
- to monitor the effect of the Model 7215 on the rate of sudden cardiac death defined as an unexpected death occurring within one hour of the onset of symptoms;
- to identify patient populations that may benefit from devices incorporating features similar to the Model 7215, and to establish criteria for selecting those patients most likely to benefit.

Data will be collected to meet the objectives cited above. These data will be utilized for Medtronic requirements, and may be used for future regulatory submissions. It is anticipated that the Model 7215 PCD as presently configured will not be market released. Performance of this device and its associated lead system may provide valid support for the next generation PCD device, Model 7216, presently under development.

TX-1426

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

RECEIVED
NOV -5 1987

OCT 30 1987

Mr. Timothy J. Johnson
Product Regulation Manager
New Products Management
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432

Re: IDE Number G870102/A1
Model 7215 Multiprogrammable Tachyarrhythmia
Control System
Dated: October 2, 1987
Received: October 3, 1987

Dear Mr. Johnson:

The Food and Drug Administration (FDA) has reviewed your investigational device exemptions (IDE) application. Your application is conditionally approved, and you may begin your investigation at the institutions listed in the enclosure after you have obtained institutional review board (IRB) approval and submitted certification of IRB approval to FDA. Your investigation is limited to 13 institutions and 30 subjects.

This approval is being granted on the condition that, within 30 days from the date of this letter, you submit information correcting the following deficiencies:

1. Based on your studies, please provide a comparison between the previous lead Models 6885, 6888, 6889, 6890 and the 6891, 6892, and the 6893 leads during sequential

pulse delivery in terms of design/construction, the amount of energy delivered as a function of voltage, impedance, pulse duration and the amount of necrotic tissue observed. The current density and uniformity of the named leads should also be discussed.

2. The results of studies that assess ventricular fibrillation (VF) sensing, electrogram signals and defibrillation threshold after multiple shocks should be provided.
3. You should submit a written confirmation that the lead Model 4951 will not be used in the Model 7215 study until further notice as discussed.
4. The informed consent should note that five leads will be implanted.

Page 2 - Mr. Timothy J. Johnson

5. The flex test results of the models 6891, 6892 and 6893 leads should be analyzed in light of the physiological environment and the requirements for epicardial leads. The expected flex areas on the leads and adapters and the design elements which will minimize the susceptibility should be identified.
6. A plan for evaluating defibrillation threshold, VF sensing and pacing thresholds at follow-up should be submitted.
7. Your proposed plan of study for evaluating the model 6893 lead in vivo should be submitted. At this time the 6893 lead is not approved for the clinical study.
8. Data that verify shelf life package integrity of the leads and pulse generator should be provided.
9. A description of the design and test data of the lithium thionyl chloride cells that are applicable in the prevention of forced overdischarge should be provided. What is the predicted duration of the elective replacement period for the lithium thionyl chloride cells?
10. The accuracy of the telemetered measurements should be included in the labeling.

This information should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, MD 20910

If you do not provide this information within 30 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

We would like to point out that FDA approval of your IDE application does not imply that this investigation will develop sufficient data to assure a determination of substantial equivalence of a premarket notification (510(k)) submission or sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance of their toll free number (800) 638-2041 or (301) 443-6597.

Page 3 - Mr. Timothy J. Johnson

We have enclosed the guidance documents entitled "Sponsor Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor. Please contact the individuals listed below if you have any questions regarding these responsibilities.

If you have any questions, please contact Mrs. Doris Terry at (301) 427-7594 or Mr. Timothy A. Ulatowski at (301) 427-8162.

Sincerely yours,

/s/ KSHITIJ MOHAN

Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

PHYSICIAN

- Gust Bardy, M.D.
1. Harborview Med. Ctr./
Seattle
- Ross Fletcher, M.D.
2. V.A. Hospital/
Washington, DC
- Charles Haffajee, M.D.
3. Univ. of MA/
Worcester, MA
- Mark Josephson, M.D.
4. Univ. of PA/
Philadelphia, PA
- Rodolphe Ruffy, M.D.
5. Jewish Hospital/
St. Louis, MO
- Sanjeev Saksena, M.D.
6. Newark Beth Israel/
Newark, NJ
- Scott Spielman, M.D.
7. Albert-Einstein - North
8. Temple Univ./
Philadelphia, PA
- Paul Troup, M.D.
9. Med. Coll. WI/
Milwaukee, WI
- Roger Winkle, M.D.
10. Sequoia Hospital/
Palo Alto, CA
- Chris Wyndham, M.D.
11. Methodist Hospital/
Houston, TX
- Douglas P. Zipes, M.D.
12. Indiana Univ. Hospital
13. Veterans Administration Hosp./
Indianapolis, IN

IRB CHAIRPERSON

- Charles Buffington
- Louis Korman, M.D.
- Marcia K. Liepman, M.D.
- Ruth Clark
- Steve Teitelbaum, M.D.
- Lester Goldman, M.D.
- Sidney Cohen, M.D.
- Peter Chapman, M.D.
- Fred Marcus, M.D.
- Frank Smith, M.D.
- Conrad Johnston, M.D.

**SPONSOR RESPONSIBILITIES
FOR A
SIGNIFICANT RISK DEVICE INVESTIGATION**

GENERAL DUTIES (21 CFR 812.40):

1. Submitting the IDE application to FDA
2. Obtaining both FDA and IRB approvals and submitting certification of IRB approval to FDA before shipping the device to any investigator
3. Obtaining FDA approval and IRB approval for a supplemental application before beginning that portion of the investigation
4. Selection of investigators
5. Ensuring proper monitoring
6. Ensuring patient informed consent is obtained

SELECTION OF INVESTIGATORS (21 CFR 812.43):

1. Assuring selection of investigators qualified by training and experience
2. Shipping the investigational device only to participating investigators
3. Obtaining a signed investigator's agreement containing:
 - a. investigator's curriculum vitae
 - b. statement of investigator's relevant experience, including dates, location, extent, and type of experience
 - c. if an investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to the termination
 - d. statement of the investigator's commitment to:
 - (1) conduct the investigation in accordance with the agreement, the investigational plan, Parts 50, 56, and 812, and any conditions of approval imposed by the IRB or FDA

- (2) supervise all testing of the device involving human subjects
 - (3) ensuring that the requirements for informed consent, Part 50 are met
4. Providing investigators with the necessary information to conduct the investigation including, but not necessarily limited to:
 - a. the investigational plan
 - b. the report of prior investigations

MONITORING (21 CFR 812.46):

1. Selecting monitor(s) qualified by training and experience to monitor the progress of the investigation
2. Securing compliance of all investigators in accordance with the signed investigator's agreement (see above for contents of that agreement), or discontinue shipment and terminate the investigator's participation in the investigation
3. Ensuring that significant new information about the investigation is provided to all reviewing IRBs, FDA, and investigators
4. Evaluating all unanticipated adverse device effects and terminating the investigation, or portions of it, if that effect presents an unreasonable risk to subjects. Reporting requirements are listed below.
5. Resuming terminated investigations only after both FDA and IRB approvals are obtained.

SUPPLEMENTAL APPLICATIONS (21 CFR 812.35(a) and (b)):

Supplemental applications are required to be submitted to, and approved by, FDA in the following situations:

1. Changes in the investigational plan: FDA approval is required for any change that may affect the scientific soundness of the investigation or the rights, safety or welfare of the subjects. IRB approval is also required for changes

that may affect the rights, safety or welfare of the subjects. The change in the investigational plan may not be implemented until both FDA and IRB approvals are obtained.

2. Addition of new institutions: IRB approval is also required for new institutions. The investigation at new institutions may not begin until both FDA and IRB approvals are obtained, and certification of IRB approval is submitted to FDA.

MAINTAINING RECORDS (21 CFR 812.140(b)): (see Table I, next page)

1. Correspondence (including reports) with another sponsor, monitor, investigators, an IRB or FDA
2. Records of shipment, including:
 - a. name and address of consignee
 - b. type and quantity of device
 - c. date of shipment
 - d. batch numbers or code marks
3. Records of disposition, describing:
 - a. Batch number or code mark of devices returned, repaired, or disposed of by the investigator or other persons
 - b. Reasons for and method of disposal
4. Signed investigator agreements
5. Adverse device effects (whether anticipated or unanticipated) and complaints

Table I
Responsibilities For Preparing and Submitting
Reports For Nonsignificant Risk Devices

____ Report Prepared By ____		
Type Of Report	Investigators For	Sponsors For
Unanticipated Adverse Effect Evaluation	Sponsors and IRBs	FDA Investigators and IRBs
Withdrawal of IRB Approval	Sponsors	FDA Investigators and IRBs
Progress Report	N/A	IRBS
Final Report	N/A	IRBs
Inability to Obtain Informed Consent	Sponsors and IRBs	FDA
Withdrawal of FDA Approval	N/A	IRBs and Investigators
Recall and Device Disposition	N/A	FDA and IRBs
Significant Risk Determinations	N/A	FDA

SUBMITTING REPORTS (21 CFR 812.150 (b)):
 (see Table II below)

1. Unanticipated adverse device effects (with evaluation) to FDA, all IRBs, and investigators within 10 working days after notification by the investigator. Subsequent reports on the effect may be required by FDA
2. Withdrawal of IRB approval
3. Withdrawal of FDA approval
4. Current 6-month investigator list
5. Annual progress report — see attached format for IDE progress report
6. Recall and device disposition

7. Final report - See attached format for progress reports
8. Use of device without obtaining patient informed consent
9. Significant risk determinations by the IRB when proposed to be nonsignificant risk
10. Other reports requested by the IRB or FDA

Table II
Responsibilities For Preparing and Submitting Reports
For Significant Risk Devices

____ Report Prepared By ____		
Type Of Report	Investigators For	Sponsors For
Unanticipated Adverse Effect Evaluation	Sponsors and IRBs	FDA Investigators and IRBs
Withdrawal of IRB Approval	Sponsors	FDA Investigators and IRBs
Progress Report	Sponsors, Monitors and IRBs	FDA and IRBs
Final Report	Sponsors and IRBs	FDA Investigators and IRBs
Emergencies (Protocol Deviations)	Sponsors and IRBs	FDA
Inability to Obtain Informed Consent	Sponsors and IRBs	FDA
Withdrawal of FDA Approval	N/A	IRBs and Investigators
Current Investigator List	N/A	FDA
Recall and Device Disposition	N/A	FDA and IRBs
Records Maintenance Transfer	FDA	FDA
Significant Risk Determinations	N/A	FDA

Suggested Format for IDE Progress Reports

I. The Basics

- IDE Number
- Device name and indication for use
- Sponsor's name, address and phone number
- Contact person

II. Study Progress

(Data from beginning of the study should be reported, unless otherwise indicated.)

- Brief summary of study progress in relation to investigational plan
- Number of investigators/investigational sites (attach list of investigators)
- Number of subjects enrolled (by indication or model)
- Number of devices shipped
- Brief summary of results
- Summary of anticipated and unanticipated adverse effects
- Description of any deviations from the investigational plan by investigators (since last progress report)

III. Risk Analysis

- Summary of any new adverse information (since last progress report) that may affect the risk analysis; this includes preclinical data, animal studies, foreign data, clinical studies, etc.
- Reprints of any articles published from data collected from this study
- New risk analysis, if necessary, based on new information and on study progress

IV. Other Changes

- Summary of any changes in manufacturing practices and quality control (including changes not reported in a supplemental application)
- Summary of all changes in investigational plan not required to be submitted in a supplemental application

V. Future Plans

- Progress toward product approval, with projected date of PMA or 510(k) submission
- Any plans to change investigation, e.g. to expand study size or indications, to discontinue portions of the investigation or to change manufacturing practices
(NOTE: Actual proposals for change should be made in a separate supplemental application).

S 3390 CONGRESSIONAL RECORD—SENATE

April 5, 1989

MEDICAL TECHNOLOGY COMPETITIVENESS ACT OF 1989

Mr. DeCONCINI. Mr. President, I take this occasion to inform my colleagues of a recent judicial decision that appears to eliminate the necessity for enacting S. 622, the Medical Technology Competitiveness Act of 1989, which I introduced on March 16.

Last week, the U.S. Court of Appeals for the Federal Circuit [CAFC] ruled that the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, permits clinical testing of medical devices during the term of an unexpired patent so long as the purpose of the testing is for submission to the U.S. Food and Drug Administration. The decision of the court thus gives the same protections and permissions to medical devices as are allowed for human drugs under Public Law 98-417.

The CAFC stated that medical devices were implicitly covered by Public Law 98-417. I agree with that decision. As I indicated when I introduced S. 622, the purpose of my bill was to clarify and to make explicit what the CAFC now says the law is. Therefore, there is no need for further legislation. I have canceled our subcommittee hearings on S. 622 which had been scheduled for April 13.

Let me take this opportunity to thank my colleagues—MR. DURENBERGER, MR. ADAMS, and MR. GORTON—for being original cosponsors of S.622. None of us desired to take sides in any legal

disputes but we felt it important to clarify Public Law 98-417 so that devices are treated explicitly under the law the same as drugs. We felt this was necessary in order to restore the proper balance in our patent laws between the rights of patent holders and the public need for technological innovation and increased competition.

**35 U.S.C. §271(e)(1) As Enacted in the Drug Price
Competition and Patent Term Restoration Act of 1984,
P.L. 98-417**

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

**35 U.S.C. §271(e)(1) As Amended in 1988 by the Generic
Animal Drug and Patent Term Restoration Act,
P.L. 100-670**

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

NOV 22 1989

JOSEPH F. SPANIOLO, JR.
CLERK

**In The
Supreme Court of the United States
October Term, 1989**

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

BRIEF FOR THE PETITIONER

TIMOTHY J. MALLOY

Counsel of Record

GREGORY J. VOGLER

LAWRENCE M. JARVIS

McANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, non-drug products?

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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 872 F.2d 402 (Pet. App. 1a).¹ The Court of Appeals denied a timely petition for panel rehearing on May 31, 1989 (Pet. App. 8a), and issued its judgment as a mandate on June

¹ Citations in this brief observe the following format. Citations to the Joint Appendix on Writ of Certiorari are in the form of "JA ____." Citations to the Appendix to the petition for a Writ of Certiorari are in the form of "Pet. App. ____." Citations to the trial transcript are by day and page in the form of "Trans. Day ____: ____." Citations to the trial exhibits are in the form of "Tr. Ex. ____."

8, 1989 (Pet. App. 14a). The Court of Appeals declined Lilly's suggestion for rehearing in banc on July 18, 1989 (Pet. App. 9a). The dissenting opinion on the denial of Lilly's suggestion for rehearing in banc is reported at 879 F.2d 849 (Pet. App. 10a).²

The memorandum decision of the United States District Court for the Eastern District of Pennsylvania rejecting 35 U.S.C. § 271(e)(1) as a defense to patent infringement for medical devices is reported at 5 U.S.P.Q. 2d 1760 (Pet. App. 15a). The district court issued a memorandum decision, 7 U.S.P.Q. 2d 1439, supporting the issuance of a permanent injunction against respondent (Pet. App. 21a). The district court further issued a memorandum decision, 696 F. Supp. 1033, directing that judgment be entered in favor of Lilly (Pet. App. 41a).

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the Court of Appeals was invoked pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1).

The decision of the Court of Appeals was entered on March 29, 1989 (Pet. App. 1a). A timely petition for rehearing was denied on May 31, 1989 (Pet. App. 8a). On August 11, 1989, the Petition for Writ of Certiorari was filed. By order dated October 10, 1989, this Court granted the Petition pursuant to 28 U.S.C. § 1254(1).

STATUTE INVOLVED

35 U.S.C. § 271(e)(1)

It shall not be an act of infringement to make, use, or sell a patented invention (other than a

² This Court (White, Justice) denied Lilly's application to stay the mandate of the Court of Appeals on July 24, 1989. This Court denied Lilly's reapplication to recall and stay the mandate of the Court of Appeals on November 6, 1989.

new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The full text of 35 U.S.C. § 271(e), including Sections 271(e)(2), (e)(3), and (e)(4), is set forth in petitioner's appendix, pp. 62a-63a, to its certiorari petition.

STATEMENT OF THE CASE

A. Factual Background

Petitioner Eli Lilly and Company ("Lilly") is an Indianapolis-based manufacturer of prescription pharmaceuticals and other products (Pet. App. 22a).³ Lilly's wholly-owned subsidiary, Cardiac Pacemakers, Inc. ("CPI"), manufactures and sells pacemakers and automatic implantable cardioverter defibrillators (Pet. App. 23a).

Respondent Medtronic, Inc. ("Medtronic") is a Minneapolis-based company (Pet. App. 23a). Medtronic is a leading manufacturer of pacemakers (Pet. App. 24a). Medtronic and CPI are competitors in the pacemaker and automatic implantable cardioverter defibrillator fields. Lilly does not compete in those fields.

³ Pursuant to Rule 28.1 of the Rules of this Court, Lilly states that it has no publicly-owned parents, subsidiaries, or affiliates.

Lilly holds the exclusive rights to the two patents in suit, U.S. Patent No. Re 27,757 (hereinafter "the '757 patent") and U.S. Patent No. 3,942,536 (hereinafter "the '536 patent") (Pet. App. 23a). Lilly has sublicensed these patent rights to CPI (*id.*).

The '757 patent is for an invention relating to an automatic implantable cardioverter defibrillator (Tr. Ex. 500). This device functions like a miniaturized emergency room which may be implanted in the body of the patient. It automatically monitors the heart through a heart-sensing lead and shocks the heart back to its normal rhythm when conditions of ventricular tachycardia (abnormally fast heartbeat) or ventricular fibrillation (fluttering of the heart muscles) occurs (Pet. App. 23a). The '536 patent is for an invention relating to a special heart-shocking lead (Tr. Ex. 501) designed to carry electrical energy from the cardioverter defibrillator unit to the heart (Pet. App. 23a). With this invention, an automatic cardioverter defibrillator may be implanted with a simple surgical procedure rather than complex open-chest surgery.

In reliance on their patent rights, Dr. Michel Mirowski and his investor toiled for ten years from the time of the invention until the world's first human implant in 1980

of a commercial embodiment of the patented invention⁴ (Trans. Day 2: 154-57). It took another five years, until 1985, before the Food and Drug Administration approved the patented product for commercial use (Tr. Ex. 600).

In 1985, Lilly paid the developers of the inventions in suit in excess of \$60 million, plus additional royalties, for the exclusive rights to the patented inventions and other assets (Trans. Day 3: 43-45; Tr. Ex. 209). Lilly immediately sublicensed its exclusive patent rights to its wholly-owned subsidiary, CPI (Pet. App. 23a). CPI, but not Lilly, makes, uses, and sells automatic implantable cardioverter defibrillators.

Pursuant to the patent laws, Lilly obtained a two-year extension on the term of the '757 patent, which thus is scheduled to expire on October 26, 1990 (Tr. Ex. 519). Lilly has not received the benefits of a patent extension for the '536 patent, which is scheduled to expire on March 9, 1993.

CPI's embodiment of the invention of the '757 patent has saved the lives of many thousands of patients:

⁴ During the summer of 1967, Dr. Michel Mirowski conceived his invention of the implantable defibrillator (Trans. Day 2: 4-8). Dr. Mirowski left his tenured position in Israel and moved to the United States to obtain the financial support needed to commercialize his invention (Trans. Day 2: 12-13). During 1970, Medtronic expressed an interest and obtained ownership of Dr. Mirowski's patent rights by assignment (Pet. App. 24a). Citing marketing reasons and technological hurdles, Medtronic abandoned the project and returned the patent rights to Dr. Mirowski in 1972 (Pet. App. 24a; Tr. Ex. 173; Trans. Day 2: 30-32). About the same time, a preeminent cardiologist published an article in a widely circulated medical journal which sharply criticized Dr. Mirowski's invention and concept (Trans. Day 2: 38-39; Tr. Ex. 515). Dr. Mirowski persevered. Ultimately, he licensed his patents to a small medical device company, Medrad (later known as Intec Systems, Inc. ("Intec")), with no prior experience in defibrillators or pacemakers (Trans. Day 2: 40-42). For several years thereafter, technical details of the implantable defibrillator were perfected until it was believed suitable for long-term human implantation (Trans. Day 2: 154-59).

Those patients [without an implantable defibrillator] who survive an episode of sudden cardiac arrest have a survival rate ranging from 30 to 60 percent during the first year after that episode.

Conventional drug therapy is often not capable of treating many surviving patients and preventing an episode of sudden cardiac arrest.

Patients who have survived an episode of ventricular tachycardia or ventricular fibrillation and who receive a CPI implantable defibrillator have a survival rate of 95 to 98 percent for the first year after their initial episode.

(Pet App. 23a-24a).

Sales of the invention have improved dramatically CPI's corporate financial picture (Pet. App. 35a; Trans. Day 3: 52-53, 55-56). The implantable defibrillator patents have given CPI an important technological advantage that has had ripple effects for its entire business. CPI has been able to attract and retain top researchers and engineers who might not have considered CPI in the past (JA 54-55). New customers' doors have been opened to CPI, and other products of CPI have gained acceptance in the medical community (JA 46-47, 54-55). In reliance on the period of exclusivity provided by the patents, CPI has introduced leading physicians to its devices and has trained them in proper device use, patient selection, surgical procedure, and post-surgical care (JA 55, 59-60).

B. Proceedings in the District Court

Pursuant to 28 U.S.C. § 1338(a), Intec brought this suit in the United States District Court for the Eastern District of Pennsylvania against respondent Medtronic. After purchasing certain Intec assets in 1985, Lilly was substituted for Intec as the plaintiff. The complaint alleged that Medtronic's development and marketing of its devices

infringed the two patents in suit. Plaintiff sought damages and injunctive relief.

In 1987, Medtronic raised as a pretrial defense a claim that it made and sold the infringing devices solely for the purpose of obtaining FDA marketing approval, and that 35 U.S.C. § 271(e)(1) immunized this activity.⁵ Section 271(e)(1) was enacted in 1984 and provided then as follows:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.⁶

The district court ruled that this section is limited to drugs and does not provide an exemption for infringing medical devices (Pet. App. 15a). The court reasoned that the statute on its face "clearly speaks" solely in terms of drugs (Pet. App. 18a-19a). "Nowhere," the district court concluded, "is there any indication that Congress had a broader intention to include medical devices within the coverage of § 271(e)(1)" (*id.* at 19a).

⁵ Although this lawsuit was initiated in 1983, Medtronic did not raise the Section 271(e)(1) defense until 1987, after Medtronic lost the reexamination proceedings on the patents in suit before the United States Patent and Trademark Office, and nearly two and one-half years after enactment of Section 271(e)(1).

⁶ Section 271(e)(1) was amended in 1988 to include certain animal products. Pub. L. No. 100-670, 102 Stat. 3971 (1988). The Court of Appeals stated that the amendment did not affect its analysis (Pet. App. 4a). As shown hereafter, however, the amendment confirms the correctness of the district court's interpretation of the statute.

Following a jury trial, the court granted a directed verdict in Lilly's favor on infringement of the '536 patent, and the jury returned a verdict in Lilly's favor on infringement of the '757 patent, including a jury finding that Medtronic willfully infringed both patents in suit (Pet. App. 22a, 35a). The district court further determined that the patents were valid and enforceable, and it directed that judgment be entered in Lilly's favor (Pet. App. 41a-42a, 55a). The court also entered a permanent injunction against Medtronic's infringement of the Lilly patents (Pet. App. 22a, 40a).

C. Proceedings in the Court of Appeals

On appeal from the injunction pursuant to 28 U.S.C. §§ 1292(a)(1) and (c)(1), the Court of Appeals reversed and remanded (Pet. App. 1a). The Court of Appeals concluded that Lilly and Medtronic had "put forth equally plausible interpretations of section 271(e)(1)," and it found both the language and legislative history of the statute to be ambiguous (Pet. App. 5a). The court ruled in Medtronic's favor, however, on the basis of an argument the court developed, *sua sponte*.

In the Court of Appeals' view, Section 271(e)(1) should be interpreted by reference not to its language, but to Congress' intent to overrule a prior case involving infringement of a drug patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). The Court of Appeals claimed there was a congressional intent to overrule *Bolar* "in all of its ramifications" (Pet. App. 7a), *i.e.*, with respect to numerous other products, including medical devices, food additives, and color additives.

Lilly timely sought rehearing and rehearing in banc. Because of the importance of the court's holding, numerous *amicus* briefs were submitted, not only by manufacturers of medical devices, but also by manufacturers of other FDA-regulated products. Additionally, Senator Orrin G. Hatch,

the principal author of Section 271(e)(1), and Representative Carlos J. Moorhead, a floor manager for the legislation, filed an *amicus* brief supporting Lilly's petition for rehearing. The panel, however, denied rehearing without opinion on May 31, 1989 (Pet. App. 8a).

On July 18, 1989, the Court of Appeals declined Lilly's suggestion for rehearing in banc (Pet. App. 9a). Judge Newman dissented on the grounds of the "exceptional importance" of the case and "the weight of the panel's error" in departing from the clear statutory language (Pet. App. 10a, 13a). Judge Newman indicated that the panel erroneously "held that the statutory words 'drugs and veterinary biological products' include medical devices" (Pet. App. 10a). Judge Newman further stated:

The panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest. Lilly, and *amici* on its behalf, observe that there are different considerations in connection with medical devices, as compared with human and animal drugs. Congress would be expected to consider the public and private economic and policy aspects of these complex industries. I cannot imagine how, on the record before us, a panel of this court can decide how Congress will decide the issue. *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) ("It is not the function of the court to amend statutes under the guise of 'statutory interpretation'").

(Pet. App. 12a-13a) (footnote omitted).

SUMMARY OF THE ARGUMENT

The decision below interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984.⁷ That provision, codified at 35 U.S.C. § 271(e)(1), states that “[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs*” (emphasis added). As both the statute’s terms and the legislative history make clear, Congress never intended the statute to apply to non-drug products.

The decision below applies the exemption in Section 271(e)(1) to a wide spectrum of non-drug products not named in the statute, including medical devices, color additives, food additives, and other products regulated by the Food and Drug Administration (“FDA”) under the Federal Food, Drug, and Cosmetic Act. The Court of Appeals concluded, *sua sponte*, that Section 271(e)(1) should be interpreted by reference not to its language, but to Congress’ intent to overrule a prior case involving infringement of a *drug* patent, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

The Court of Appeals’ decision contravenes the plain language of Section 271(e)(1), its legislative history, and sound public policy. The statute expressly restricts its application to uses relating solely to the development of information for submission under “a Federal law which regulates . . . drugs.” By its terms, this refers to submissions under 21 U.S.C. § 355, the federal statute prohibiting introduction of a new drug into interstate commerce without prior approval by the FDA. It would be odd, to say the least, for Congress to identify the premarket approval requirements for medical devices, food additives, and color

additives as being set forth in a law “which regulates . . . drugs.”

Had Congress intended to apply Section 271(e)(1) to medical devices and other FDA-regulated articles in addition to drugs, it would have identified submissions under the “Federal Food, Drug, and Cosmetic Act”—a term used only a few lines earlier in the same subsection. It conflicts with basic tenets of statutory construction to assume that Congress used a different (and facially more restrictive) term to refer to the same Act elsewhere in Section 271(e)(1). Congress would have continued to identify the Federal Food, Drug, and Cosmetic Act by name in the operative language of Section 271(e)(1) if it in fact intended the infringement exemption to apply to any use under that Act.

Other provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 demonstrate that Congress intentionally limited Section 271(e)(1) to drugs. For example, the companion Sections 271(e)(2) and (e)(4), which qualify Section 271(e)(1), indisputably are restricted to the enumerated products, *i.e.*, drugs and veterinary biological products. Section 271(e)(1) must be construed in the same manner. Within the same Act, Congress expressly included drugs, medical devices, food additives, color additives, and veterinary biological products in 35 U.S.C. § 156(f), while expressly identifying only drugs and veterinary biological products in Section 271(e)(1). This disparate inclusion and exclusion demonstrates that Congress purposely excluded medical devices from Section 271(e)(1).

Since the statutory language is clear, there was no reason for the Court of Appeals to examine the legislative history of Section 271(e)(1). Having done so, however, the court below seriously misconstrued that history. Each of the statements referring expressly to the class of products affected by Section 271(e)(1) indicates that Congress

⁷ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

intended it to apply solely to drugs. There is not a single statement in the legislative history suggesting that any legislator believed that it would apply to medical devices or other non-drug products. Generalized references to overruling the holding of the *Bolar* case—which itself involved a drug patent, not a device patent—are no basis for disregarding the statutory language and specific statements in the legislative history as to the scope of Section 271(e)(1). Congress understood the holding of that case to relate only to drugs, and the Court of Appeals should have interpreted the statute consistent with Congress' understanding.

Finally, there is a sound policy basis for distinguishing between drug and device patents in Section 271(e)(1). The premarket bioequivalence testing required for approval of generic copies of patented drugs is quite limited by comparison with the extensive clinical trials required for approval of new medical devices such as CPI's implantable defibrillator. Drug bioequivalence testing is conducted in a small number of healthy volunteers, and does not take customers away from the patent holder. Device testing, by contrast, requires testing in patients with the disease or condition under study, and clinical trials may take away millions of dollars in sales from the device patent holder. Such losses can be expected to stifle device innovation, to the detriment of the public health. For these reasons, the fact that Congress authorized limited drug testing prior to patent expiration is no basis for presuming that Congress also intended to permit the much greater inroads on patent rights that pre-expiration device testing would entail.

The decision below is quite clearly wrong. It constitutes impermissible judicial legislation to expand the limited scope of Section 271(e)(1).

ARGUMENT

This is not an ordinary patent case. It involves the construction of a federal statute that will have, unless reversed, a significant negative impact on investment in health-care research and development, and on the pace of innovation in lifesaving medical devices. Medical devices are subject to premarket approval and other regulation by the FDA. Prior to the Court of Appeals' decision in this case, it would have been an act of patent infringement to make, use, or sell an infringing product in studies conducted to obtain the data necessary for FDA approval for medical devices or other non-drug products. The Court of Appeals interpreted a narrow statutory exemption, which universally had been understood to apply *only* to the limited testing necessary for generic drug approvals (JA 27-28), to encompass studies for *all* FDA-regulated products. That decision is incorrect as a matter of law.

I. The Statutory Language Expressly Limits Section 271(e)(1) to Drugs and Veterinary Biological Products and Does Not Encompass Medical Devices and Other FDA-Regulated Products

A. The Plain Meaning of the Statute Is Directly Contrary to the Court of Appeals' Decision

The United States patent laws broadly provide that "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). In its present form, 35 U.S.C. § 271(e)(1) provides a limited exception to the broad infringement statute:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug,

and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products (emphasis added).

35 U.S.C. § 271(e)(1).⁸

"Interpretation of a statute must begin with the statute's language." *Mallard v. U.S. District Court for the Southern District of Iowa*, ___ U.S. ___, 109 S.Ct. 1814, 1818 (1989). The ordinary reading of the quoted statutory language grants a narrow exemption from patent infringement for developing information necessary to obtain approval for "drugs" and "veterinary biological products," the specifically enumerated categories. "Medical devices" are not mentioned. Indeed, medical devices are expressly excluded from the definition of the term "drug" under the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. § 321(g)(1) ("The term 'drug' . . . does not include devices or their components, parts, or accessories."). Drugs and devices are regulated under entirely different statutory

⁸ The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988). While subsequent amendments cannot substitute for a clear expression of legislative intent at the time of enactment, "they should not be rejected out of hand as a source that a court may consider in the search for legislative intent." *Andrus v. Shell Oil Co.*, 446 U.S. 657, 666 n.8 (1980). Here, the subsequent amendments confirm that Section 271(e)(1) is product specific, excluding medical devices.

provisions. Compare 21 U.S.C. § 355 (drugs) with 21 U.S.C. § 360 (devices).

This should have been the end of the matter. The courts are bound by the specific statutory language in construing statutory provisions. See, e.g., *United States v. James*, 478 U.S. 597, 604-606 (1986). Inexplicably, however, the Court of Appeals has read the provision to grant an exemption from patent infringement not only for drugs and veterinary biological products, but also for developing information necessary to obtain approval of a wide spectrum of other products requiring FDA approval, most significantly, medical devices.⁹

The Court of Appeals' interpretation undeniably requires a strained reading of the plain language of the statute.¹⁰ To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the entire Federal Food, Drug, and Cosmetic Act, including the device provisions, as well as the Biologics Act of 1902. This reading is directly refuted by the plain language of the statute: a few lines earlier in Section 271(e)(1), Congress referred expressly to the

⁹ The Court of Appeals' reading also effectively changes patent infringement law with respect to food additives and color additives. See 21 U.S.C. §§ 348, 376; 21 C.F.R. §§ 71.1, 171.1 (1988) (describing data submission requirements for food additive petitions and color additive petitions).

¹⁰ The Court of Appeals' reliance on *United States v. Fausto*, 484 U.S. 439 (1988) (Pet. App. 6a), does not support its departure from the statutory language. Rather, that case confirms the importance of both the language chosen by Congress and the congressional intent. The instant case raises no question requiring the reconciliation of interrelated laws enacted at different times. Rather, it requires only a straightforward exercise in the interpretation of Section 271(e)(1) based on its plain language and legislative history.

"Federal Food, Drug, and Cosmetic Act." The Court of Appeals' reading cannot be squared with the language of Section 271(e)(1).

In contrast with petitioner's straightforward reading of the statute, the Court of Appeals erred by giving, in effect, the same meaning to different phrases in the same statute. It is unreasonable to assume that Congress used the term "law which regulates . . . drugs" to mean the entire Federal Food, Drug, and Cosmetic Act, when it identified the statute by name in Sections 271(e)(1) and (e)(2). See, e.g., *Colautti v. Franklin*, 439 U.S. 379, 392-93 (1979) (rejected theory that "may be viable" means "viable" within the same statute); *Russello v. United States*, 464 U.S. 16, 23 (1983) (rejected argument that differing language in two subsections of a statute had the same meaning); *National Insulation Transportation Committee v. Interstate Commerce Commission*, 683 F.2d 533, 537 (D.C. Cir. 1982) ("the use of different terminology within a statute indicates that Congress intended to establish a different meaning"). In short, if Congress had meant to exempt any experimental use of medical devices for premarket approval under the Federal Food, Drug, and Cosmetic Act, it would have said so expressly. The Court of Appeals erred by concluding otherwise.

The decision below also is inconsistent with the holdings of the few courts that have considered the issue prior to the ruling. The district court in the instant case, as well as the only other district court to have discussed the issue, concluded that Section 271(e)(1) is limited to drugs. See Pet. App. at 19a ("the § 271(e)(1) defense [is] inapplicable to medical devices"); *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 U.S.P.Q. 2d 1562, 1565 (D. Del. 1988) ("It is also clear that Section 271(e)(1) applies only to drugs, not to medical devices." (dictum citing the district court's decision in this case)).

B. The Remaining Sections of 35 U.S.C. § 271(e) Limit Section 271(e)(1) to Drugs and Veterinary Biological Products

The argument for a broad construction of Section 271(e)(1) is refuted by the companion Sections (e)(2) and (e)(4). Sections 271(e)(2) and (e)(4) qualify Section 271(e)(1). *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 231 U.S.P.Q. 978, 980 (N.D. Cal. 1986) (Section 271(e)(2) "limits the scope of the preceding [Section 271(e)(1)]"); *Eli Lilly and Company v. Premo Pharmaceutical Laboratories*, 4 U.S.P.Q. 2d 1080, 1083 (D.N.J. 1987), *aff'd*, 843 F.2d 1378 (Fed. Cir. 1988) ("Section 271(e)(2) qualifies [Section 271(e)(1)]"). These sections indisputably are restricted to specifically-identified products, i.e., drugs and veterinary biological products.

Congress included protections—by specifying acts of infringement and establishing remedies—for drug patent holders under certain circumstances in Sections 271(e)(2) and (e)(4) (Pet. App. 62a-63a). Congress added similar protections for owners of patented animal products in the 1988 amendment to Section 271(e) (*id.*). Had Congress intended medical devices to fall within the infringement exemption of Section 271(e)(1) as originally enacted, surely Congress would have provided corresponding protections for patent holders of medical device inventions in the original enactment of Sections 271(e)(2) and (e)(4).¹¹ However, the current Sections 271(e)(2) and (e)(4) are specific to "drugs" and "veterinary biological products" and thus further confirm that their companion Section 271(e)(1)

¹¹ For example, proposed Senate Bill S.622 would add "medical devices" to Sections 271(e)(1), (e)(2) and (e)(4) (Pet. App. 60a-61a). After-the-fact congressional activity is no substitute for the statutory language and congressional intent at the time of the enactment for purposes of statutory interpretation. However, the subsequently proposed bill is consistent with the 1984 enactment.

should be construed in the same manner. *See, e.g., Sedima S.P.R.L. v. Imrex Company, Inc.*, 473 U.S. 479, 489 (1985) ("should not lightly infer that Congress intended the term to have wholly different meanings in neighboring subsections").

The Court of Appeals' decision inserts the words "medical devices" into Section 271(e)(1) without providing the additional patent protections of Sections 271(e)(2) and (e)(4). This is the worst possible result for medical device patent holders and was never expressed or intended by Congress.

C. Other Provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 Demonstrate that Section 271(e)(1) Was Limited Intentionally to Drugs

Congress added Section 271(e)(1) to the patent statute as part of a broader enactment.¹² Courts must interpret the various sections of the same law, concerning the same subject, together to avoid conflicts and to assure consistency. *See, e.g., United States v. Morton*, 467 U.S. 822, 828 (1984); *In re Nantucket, Inc.*, 677 F.2d 95, 98 (C.C.P.A. 1982). In both the Drug Price Competition and Patent Term Restoration Act of 1984 (the "1984 Act") and the Federal Food, Drug, and Cosmetic Act ("FD&C Act") to which the 1984 Act refers, Congress distinguished between "drugs" and "devices." *See* pages 13-15, *supra*. This Court should construe Section 271(e)(1) together with the other provisions of the 1984 Act and the FD&C Act.

¹² On September 24, 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The 1984 Act consists of two relevant titles: Title I addresses "Abbreviated New Drug Applications" (ANDA), and Title II covers "Patent Term Restoration." Title II of the 1984 Act is relevant because it amended the Patent Act by adding 35 U.S.C. § 271(e) and 35 U.S.C. § 156.

In the patent extension provisions of the 1984 Act, when Congress intended to extend the patent life for inventions covering both drugs and medical devices, it said so expressly. Congress explicitly stated that the patent extension provisions apply to "products" subject to a regulatory review period before commercial marketing or use. 35 U.S.C. § 156(a)(4). Congress then expressly identified the products involved:

- (A) A human drug product.
- (B) Any medical device, food additive, or color additive subject to regulation under the *Federal Food, Drug, and Cosmetic Act*.

35 U.S.C. § 156(f)(1) (1984) (emphasis added). It is noteworthy that the phrase used in Section 271(e)(1)—"a Federal law which regulates the manufacture, use, or sale of drugs" was not used. Instead, Congress used the phrase "under the Federal Food, Drug, and Cosmetic Act."

If Congress had intended to provide an infringement exemption for devices as well as for drugs, it would have referred to a law which regulates "drugs and devices." Whenever Congress limited a patentee's rights under Section 271(e)(1) or provided patent extension rights

under Section 156, Congress spoke clearly.¹³ Congress used clear language to identify "drugs" under the Section 271(e)(1) exemption and the Section 156 extension provisions in the 1984 original enactment. Congress used clear language to identify that under limited circumstances, medical device, food additive, and color additive patents qualified for patent extensions under Section 156. Congress' 1988 amendment of the statute extended the exemption and patent extension rights to certain animal drugs and veterinary biological products. Congress did so by adding the express reference to "veterinary biological products" and deleting the exclusion for certain animal drugs from the "drug" category in Sections 271(e) and 156. See Pub. L. No. 100-670, 102 Stat. 3971, 3988 (1988).

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello*, 464 U.S. at 23 (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)). Within the same Act, Congress expressly included drugs, veteri-

¹³ Section 271(e)(1) is not a *quid pro quo* accepted for the enactment of 35 U.S.C. § 156, the patent extension provisions of the Patent Act. The legislation that eventually led to enactment of 35 U.S.C. § 156 had been before Congress since 1980, well before the 1984 *Roche* decision which prompted enactment of Section 271(e)(1). See S.2892, 96th Cong. 2d Sess. (1980). Moreover, the two statutes are not, and never were intended to be, coextensive. Section 271(e)(1) applies even during the original term, and not just to the extended term, of patents that have been extended. Section 271(e)(1) also applies to many patents that do not meet the numerous eligibility requirements for extension under Section 156(a). Cf. *Fisons v. Quigg*, 872 F.2d 99 (Fed. Cir. 1989) (discussing eligibility restrictions). As is the case generally with the vast majority of medical device patents, Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.

nary biological products, medical devices, food additives, and color additives in 35 U.S.C. § 156(f) while expressly identifying only drugs and veterinary biological products in 35 U.S.C. §§ 271(e)(1), (e)(2) and (e)(4). This disparate inclusion and exclusion is no accident.¹⁴ The principle of statutory construction espoused in *Russello* controls, and Section 271(e)(1) must be interpreted to exclude purposely medical devices, food additives, and color additives.

D. The Operative Language of Section 271(e)(1) Is Not "Patented Invention" as Alleged by Respondent

The term "patented invention" is the term used in 35 U.S.C. § 271(a) which Section 271(e)(1) modifies. Section 271(e)(1) follows a similar form. However, the operative language of Section 271(e)(1) is the phrase "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." This operative language modifies and restricts the term "patented invention" within the Section 271(e)(1) exemption.

Although the Court of Appeals did not accept the argument, Medtronic urged below that the statutory language was ambiguous because Congress referred to the term "patented invention" rather than to the terms "drug" or "patented human drug product." In its brief in opposition to Lilly's petition for a writ of certiorari, Medtronic changed its argument. Medtronic now says Congress could have used the term "drug invention" (Respondent's Brief in Opposition, p. 8).

¹⁴ The district court held that "other sections of the [Drug Price Competition and Patent Term Restoration Act of 1984] distinguish between 'drugs' and 'devices,' further indicating that when Congress intended to include devices within the coverage of a section, it clearly specified as much, rather than assume the term 'drugs' to include 'devices' "(Pet. App. 18a).

The use of the term "patented invention" is explicable because Congress was dealing not only with product patents but also with patents for drug compositions and patents for uses of drugs. Thus, the terms "patented drug" or "drug invention" would have been potentially unclear as to whether it was limited to product patents, whereas the term "patented invention" covers patents for drug products, as well as drug composition and drug use. In addition, the use of the term "patented invention" is consistent with 35 U.S.C. § 271(a).

II. The Court of Appeals Misused the Legislative History to Reach a Decision Inconsistent with Congress' Clear Language and Intent

The Court of Appeals erred by disregarding the plain language of Section 271(e)(1) in favor of a broader policy allegedly expressed in the legislative history. See, e.g., *Burlington Northern Ry. Co. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987) (in the absence of ambiguity, statutory language is conclusive). There is no ambiguity in Section 271(e)(1). The phrase "under a Federal law which regulates the manufacture, use, or sale of drugs" cannot mean "under a Federal law which regulates the manufacture, use, or sale of drugs and medical devices." The Court of Appeals and Medtronic use isolated statements in the legislative history not to resolve doubt, but to create it. See, e.g., *Railroad Commission of Wisconsin v. Chicago B. & Q. Ry. Co.*, 257 U.S. 563, 589 (1922) ("[Committee reports] are only admissible to solve doubt and not to create it.").

In any event, the legislative history contradicts the Court of Appeals' decision and further demonstrates that Congress intended for Section 271(e)(1) to allow limited infringement only for drugs (and later for animal products), but not for any other FDA-regulated product. There is not a single reference in the legislative history of this provision

suggesting the possibility of exempting infringement of medical device patents.

Two committee reports were prepared on the 1984 legislation originally enacting Section 271(e)(1): one by the House Committee on Energy and Commerce and one by the House Committee on the Judiciary. H.R. Rep. No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984). Both reports unambiguously establish that Section 271(e)(1) is directed solely to drugs.

The Committee on Energy and Commerce stated:

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of [A]ppeals for the Federal Circuit held that this type of experimentation is infringement.

In *Roche . . .*, the Court of Appeals for the Federal Circuit held that the experimental use of a *drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.

H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 45-46 (1984) (emphasis added). See, e.g., *id.*, Part 1, at 15 ("Title II provides that it is not an act of patent infringement for a *generic drug* maker to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added)); *id.*, Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval of *the drug*." (emphasis added)); *id.*, Part

2, at 27 n.18 (it would not be infringement to make, use, or sell a patented invention "for the purpose of obtaining FDA premarketing approval of a *drug*" (emphasis added)); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to animal products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986) (emphasis added).¹⁵

The Court of Appeals inexplicably dismissed these clear expressions of congressional intent as merely "general statements . . . which allegedly support" the district court's interpretation of the statute (Pet. App. 5a). At the same time, its opinion (*id.*) gives the erroneous impression, without citation, that there are contrary statements supporting the extension of Section 271(e)(1) to devices. There are none. See Pet. App. 5a-7a.

The Court of Appeals concluded *sua sponte*, however, that Section 271(e)(1) was intended to overrule the *Bolar* case, *supra*, "in all of its ramifications" (*id.* at 7a) and thereby to immunize infringement for medical devices and other products not mentioned in the statute itself, in its legislative history, or in the *Bolar* case. This interpretation defies comprehension and is contrary to accepted principles of statutory construction.

¹⁵ Commentators on the 1984 legislation agreed that this provision "is limited to human drug products, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L. J. 269, 308 (1985); JA 24-28; accord, Fox & Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984*, at 178, 187 (Food and Drug Law Inst. 1987).

Congress intended Section 271(e)(1) to "have the net effect of reversing the *holding*" in *Bolar*. H.R. Rep. No. 857, *supra*, Part 2, at 27 (emphasis added). Congress understood the court in that case to have "held that the experimental use of a *drug product* prior to the expiration date of a patent claiming that *drug product* constitutes patent infringement." *Id.*, Part 1, at 45-46 (emphasis added); accord, *id.*, Part 2, at 27 n.18. In *Bolar* itself, the Court of Appeals stated that the issue was a "narrow" one:

does the limited use of a *patented drug* for testing and investigation strictly related to FDA *drug* approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

733 F.2d at 861 (emphasis added). Whatever the Court of Appeals now believes its holding to have been, surely it is Congress' understanding at the time it enacted Section 271(e)(1) that is relevant.¹⁶ Thus, Congress overruled *Bolar* "in that (Section 271(e)(1)) would provide that the generic *drug* manufacturers can start playing around with the *drug* on which the patent is about to expire." 130 Cong. Rec. H8712 (daily ed. Aug. 8, 1984) (statement of Rep. Kindness) (emphasis added).

It is difficult to imagine how Congress could have made its intentions any more clearly known. There is simply no basis for concluding that Congress intended anything more than to overrule the precise holding of *Bolar* as Congress

¹⁶ "The meaning and effect of legislation whose operation is conditioned by common-law principles *are not changed by subsequent judicial decisions* modifying the common-law principles." 2a *Sutherland Statutory Construction* § 50.02, at 431 (4th ed. 1984) (emphasis added). See generally, e.g., *Mackey v. Lanier Collections Agency & Service, Inc.*, 486 U.S. 825, 108 S.Ct. 2182, 2191 (1988) (" 'It is the intent of the Congress that enacted [the section] . . . that controls.' ") (citations omitted).

and the *Bolar* court understood it, i.e., a prohibition on the experimental use of patented drugs for FDA approval purposes. The Court of Appeals here pointed to no evidence of congressional intent, and there is none, suggesting a desire to overrule *Bolar* "in all of its ramifications."¹⁷ The court's *ipse dixit* thus entirely ignores the plainly expressed intention of Congress.

III. The Court of Appeals' Decision Constitutes Impermissible Judicial Legislation

The Court of Appeals' error is all the more apparent because its reading is not limited to devices. It applies also to every other article regulated under the FD&C Act, such as food additives, color additives, and other substances—none of which is referred to anywhere in the infringement exemption of Section 271(e)(1) or in the protections afforded patent holders in Sections 271(e)(2) and (e)(4). In short, the Court of Appeals expanded a statute that by its terms allowed only a narrow infringement exemption for two specifically enumerated products—drugs and veterinary biological products—to apply to medical devices and other products not mentioned anywhere in the statute itself.

The Court of Appeals' decision seems to be based upon its own view of possibly applicable policy considerations (Pet. App. 7a, 13a). The Court, however, was not free to substitute its policy choices for those of Congress and

¹⁷ Moreover, if Congress intended to overrule all of the "ramifications" of *Bolar*, this would eliminate the experimental-use exception to patent infringement for all inventions, not just for those pertaining to FDA-regulated products. See *Bolar*, 733 F.2d at 862-63. Congress of course intended no such thing, and not even the Court of Appeals suggests that it did. Yet the court offered no justification for picking and choosing among the various "ramifications" of *Bolar* that purportedly were overruled by Section 271(e)(1). The only interpretation that can be defended on the basis of the statutory language and legislative history is that Congress intended to overrule *Bolar* as it applied to drugs.

rewrite the legislation.¹⁸ See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy."); *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 456 (1984), ("it is not our job to apply laws that have not yet been written"); *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952) ("It is our judicial function to apply

¹⁸ The extent of the Court of Appeals' departure from both the words of the statute and Congress' expressed intent is suggested by the fact that its interpretation, extending Section 271(e)(1) to medical devices and other products, was totally unexpected by those in the medical device manufacturing community familiar with the statute. See *amicus* briefs supporting Lilly's petition for certiorari. The Declaration of Peter Barton Hutt, who represented the Pharmaceutical Manufacturers Association in consideration of this legislation and served as a moderator at the Food and Drug Law Institute's briefing on the Drug Price Competition and Patent Term Restoration Act, sets forth the contemporaneous industry involvement regarding Section 271(e)(1) (JA 16, 27-28). The legislative history of Section 271(e)(1) made no reference at all to medical devices, and the medical device industry had no input on the issues relevant to applying Section 271(e)(1) to medical devices (JA 28).

If Congress had intended to include medical devices within the ambit of Section 271(e)(1), it is inconceivable that medical device patent holders would have had no involvement in the process and no opportunity to provide Congress with information on the significant, adverse effects of such legislation on a vitally important high technology industry and on the public. The conclusion that there would have been input from the medical device industry if Section 271(e)(1) was intended to reach medical devices is reinforced by the fact that the legislative history of the 1984 legislation clearly shows that Section 271(e)(1) was drafted after extensive input from both generic and innovator drug manufacturers. See, e.g., 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs"); *id.* at H8706-07 (daily ed. Aug. 8, 1984) (statements of Reps. Kastenmeier and Waxman).

statutes on the basis of what Congress has written, not what Congress might have written.”).

As Judge Newman concluded, the Court of Appeals’ departure from the statutory language constitutes impermissible judicial legislation (Pet. App. 12a). The Court of Appeals did not heed this Court’s earlier warning:

Our individual appraisal of the wisdom or unwisdom of a particular course consciously selected by the Congress is to be put aside in the process of interpreting a statute. Once the meaning of an enactment is discerned and its constitutionality determined, the judicial process comes to an end. We do not sit as a committee of review, nor are we vested with the power of veto.

Tennessee Valley Authority v. Hill, 437 U.S. 153, 194-95 (1978).

IV. Public Policy and Constitutional Considerations Require Reversal of the Court of Appeals’ Decision

The application of Section 271(e)(1) only to drugs, which is compelled by its language as well as its legislative history, is further supported by important distinctions between FDA regulation of drugs and medical devices.¹⁹ While the Court

¹⁹ Petitioner is well aware of this Court’s holding:

Since our present task is one of statutory construction, questions of public policy cannot be determinative of the outcome unless specific policy choices can be attributed to Congress itself.

Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 220-21 (1980). However, Lilly feels compelled to address the Court of Appeals’ statement that there is “[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only” (Pet. App. 7a). The distinctions between the FDA regulations for drugs and medical devices also demonstrate the constitutional problems associated with the Court of Appeals’ interpretation.

of Appeals claimed to discern “[n]o persuasive reason . . . why Congress would create an exception with respect to those activities for drugs only” (Pet. App. 7a), there are in fact sound policy considerations favoring this interpretation. The court apparently failed to appreciate these reasons because it lacked a sufficient understanding of the very different FD&C Act provisions and FDA regulations that govern testing and approval of drugs versus medical devices. See Judge Newman’s dissenting opinion, Pet. App. 12a (“there are different considerations in connection with medical devices, as compared with human and animal drugs”). The extension of the infringement exemption to medical devices is unsupported as a matter of sound policy and serves only to retard the development of innovative health products.

New drugs are subject to premarket approval by the FDA upon a showing of safety and effectiveness. See 21 U.S.C. § 355. Prior to 1984, generic copies of previously-approved drugs generally required their own approvals resting on their manufacturers’ own clinical studies. See *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983). The same statute that enacted Section 271(e)(1) also established an “abbreviated” procedure for approval of generic drugs. See 21 U.S.C. § 355(j). Under this procedure, an applicant for generic approval is not required to submit independent proof of safety and effectiveness, but need show only that its product is “bioequivalent” to the previously-approved drug—i.e., that it has the same “rate and extent of absorption” into the bloodstream. 21 U.S.C. § 355(j)(7)(B)(i).

Section 271(e)(1) permits such bioequivalence testing prior to the expiration of a drug patent. This testing is conducted in a limited number of volunteers, typically healthy persons who do not even have the disease for which the drug is intended. These persons are not charged for the drug. Congress found that the “nature of the interfer-

ence" with a drug patent holder's rights entailed by such bioequivalence testing "is *de minimis*." H.R. Rep. No. 857, Part 2, at 30.²⁰

The interference with a medical device patent holder's rights, however, is far more significant. There is no "abbreviated" procedure for premarket approval of medical devices. See 21 U.S.C. § 360. The medical device testing that would be permitted under the Court of Appeals' decision therefore encompasses full-scale clinical trials rather than the much more limited bioequivalence testing necessary for generic drug approval.

Medical device clinical trials permit manufacturers to introduce their products to the market by treating patients with the underlying disease (JA 39-42). Leading physicians and medical institutions are involved in the studies (JA 146). Many devices, such as the implantable defibrillators at issue here, are permanently implanted and thus each patient who is treated with the investigational device is unavailable as a customer to the patent holder. Similarly, many devices, such as diagnostic instruments, have only a small number of potential customers. Hospitals, for example, may need only one CAT-scan machine, and thus each hospital using an infringing device, even for "investigational" purposes, is lost to the patent holder's market.

Moreover, manufacturers charge for investigational devices, even those that infringe patents. See 21 C.F.R. § 812.7(b). Such charges are common, especially for expensive devices such as implantable defibrillators. Medtronic, for

²⁰ While the statute also would permit clinical trials of patented drugs, Congress understood that, as a practical matter, manufacturers would take advantage of the much faster and less expensive "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own time-consuming clinical tests in hundreds or thousands of patients. See H.R. Rep. No. 857, Part 2, at 8.

example, sold its infringing units for \$17,000 each and originally projected (but did not achieve) eleven million dollars of infringing sales—all, according to Medtronic, during clinical trials. (Pet. App. 12a n.4). Some medical devices may carry even higher per-item prices. Indeed, a single medical device itself may be sold for a quarter of a million dollars or more. Clinical trials by infringers could rob patent holders of millions of dollars in lost sales, while the infringers themselves recover all of their "costs of manufacture, research, development, and handling" (21 C.F.R. § 812.7(b))—all before the life of the patent has expired.

Accordingly, there are persuasive reasons—rooted in the different testing procedures and approval requirements of drugs and devices—for distinguishing between them in Section 271(e)(1).²¹ Those differences raise a serious constitutional question under the takings clause of the Fifth Amendment of the U.S. Constitution if the statute is interpreted to authorize the infringing use of medical devices. Cf. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018-19 (1984). Section 271(e)(1), as interpreted by the Court of Appeals, impermissibly takes a portion of the exclusive patent rights from medical device patent holders *after* a patent holder has disclosed its invention to the public. Such public disclosure is the *quid pro quo* for the exclusive patent right for the *entire* patent term. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, ___ U.S. ___, 109 S.Ct. 971, 977 (1989).

²¹ Although not adopted by the Court of Appeals, Medtronic alleges that the district court's interpretation of Section 271(e)(1) results in a *de facto* extension of certain patents. Medtronic could have avoided any alleged *de facto* extension of the patents in suit. Medtronic's expert trial witness, Mr. Paul Wylie, testified under oath that Medtronic can easily obtain FDA approval prior to patent expiration based on activities outside the United States that would not infringe the patents in suit (JA 107-8). See also 21 C.F.R. § 814.15 (regulations permit FDA approval of medical devices based solely on foreign activities).

("The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.").

When it enacted Section 271(e)(1), Congress addressed this takings question as it applied to drugs, and it concluded that the statute was constitutional largely because of the "de minimis economic impact" on drug patent holders:

[T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. . . . Thus, the nature of the interference with the rights of the patent holder is not substantial.

H.R. Rep. No. 857, Part 2, at 8; *see also id.*, Part 2, at 27-30; *id.*, Part 1, at 46 (Bioequivalence is equivalence in the rate and extent of absorption of a drug. *See* 21 U.S.C. § 355(j)(7)(B)(i)).

The much more substantial economic impact of an infringement exemption for medical devices raises a correspondingly more substantial constitutional issue. That issue would be avoided, as it should be, by interpreting Section 271(e)(1) in accordance with its plain meaning and legislative history to apply only to drugs and veterinary biological products. *See generally Ashwander v. Tennessee Valley Authority*, 297 U.S. 288, 346-348 (1936) (Brandeis, J., concurring); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 108 S.Ct. 1392, 1397 (1988) ("where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress").

Finally, the Court of Appeals' decision will have a significant deleterious effect on medical device innovation, and therefore on public health. The patent system is intended to provide the necessary incentive for "inventiveness and research efforts." *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980). That incentive would be seriously eroded if infringement is immunized for device testing purposes.

The decision below will discourage precisely what the patent laws are intended to encourage—innovation, technological development, and investment in high-risk ventures, such as the automatic implantable cardioverter defibrillator. The absence of full patent protection will encourage copying instead and merely benefit the imitators of innovators.

At the same time that it enacted Section 271(e)(1), Congress provided for the partial extension of drug and device patents in order to "create a significant, new incentive which would result in increased expenditures for research and development" in the health-care industry. H.R. Rep. No. 857, *supra*, Part 1, at 18. While Congress was willing, as part of a compromise with generic drug interests, to make a *de minimis* exception for drug bioequivalence testing, it did not make the much larger inroad on patent rights that a device exception would represent. Such an exception would eviscerate the very research incentives that Congress had intended to expand in the 1984 legislature. As Judge Newman concluded, "[t]he panel's judicial legislation has affected an important high-technology industry, without regard to the consequences for research and innovation or the public interest" (Pet. App. 12a).

CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Appeals for the Federal Circuit should be reversed, and this case should be remanded with instructions to enter judgment in favor of the petitioner and to reinstate the district court's original injunction.

Respectfully submitted,

TIMOTHY J. MALLOY

Counsel of Record

GREGORY J. VOGLER

LAWRENCE M. JARVIS

McANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

312/707-8889

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT

Of Counsel:

ARTHUR R. MILLER
1563 Massachusetts Ave.
Cambridge, Massachusetts 02138

RONALD E. LUND
JOSEPH BREIMAYER
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432

JOHN F. LYNCH
Counsel of Record

W. BRYAN FARNEY
W. DAVID WESTERGARD
ALBERT B. DEEVER
ARNOLD, WHITE & DURKEE
Houston, Texas 77057
(713) 787-1400

Counsel for Respondent

Alpha Law Brief Co., Inc. — 8748 Westpark—Houston, Texas 77063 — 789-2000

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QUESTION PRESENTED

Whether a patent can be employed to foreclose experimental testing of medical devices to develop and submit information under the Federal Food, Drug and Cosmetic Act despite the existence of 35 U.S.C. § 271(e)(1) which declares it is not an act of patent infringement to "make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs."

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STATEMENT

A. The Statutory Scheme

The Food and Drug Administration ("FDA") regulates various products including human and animal drugs, medical devices, food additives, and color additives. Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301-93 (1982 & Supp. I 1983 - Supp. V 1987), as amended by Pub. L. No. 100-670, 102 Stat. 3971 (1988); Public Health Service Act ("PHS Act"), 42 U.S.C. §§ 262-63 (1982 & Supp. V 1987). There are products in each of those categories that must be tested and approved before being sold to the general public. The testing necessary to secure FDA approval can be extensive and time-consuming.

The resulting regulatory delay in getting to market inherently conflicts with the goals and operation of the patent laws. The ability to exploit a patent monopoly may be minimal during those early years of a patent when the patentee is attempting to comply with regulatory prerequisites imposed by the FDA. Hence, the patentee's overall period of market exclusivity is effectively reduced from the seventeen years granted by the patent laws. Conversely, competitors seeking to enter the market with a competitive or improved invention after expiration of a patent are delayed by their own need to qualify their inventions under the FDA regulatory process. If that testing cannot be done until after the patent expires, the patentee enjoys an additional post-patent period of market exclusivity which Congress has called a "secondary patent."¹ Thus, FDA testing requirements

1. H. Rep. No. 972, 100th Cong., 2d Sess., pt. 2, 15 (1988). It also has been dubbed a "regulatory patent":

Once a manufacturer has gone through the [FDA pre-market approval] process, it gains what has been termed a "regulatory patent." That is, until other manufacturers of similar products go

can produce both a *de facto* reduction and a *de facto* extension of the patent term.

Congress dealt with those problems by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("DPC-PTR Act"). Two interrelated parts of Title II of the Act bear on the problems of *de facto* alteration of patent rights by FDA testing requirements. 35 U.S.C. §§ 156 & 271(e) (1982 & Supp. V 1987), *as amended* by Pub. L. No. 100-670, 102 Stat. 3971 (1988). The Act's provisions for extending the patent term counteract the *de facto* reduction by providing an express patent extension related to the amount of time necessary to secure FDA approval. § 156. Patent term extension explicitly is made available to drug products and to "[a]ny *medical device* . . . subject to regulation under the Federal Food, Drug and Cosmetic Act." § 156(f)(1) (emphasis added). The Act also contains a provision that counteracts the *de facto* extension by permitting an otherwise-infringing "patented invention" to be used to develop information reasonably related to obtaining FDA regulatory approval. § 271(e)(1).

through the PMA process, the manufacturer with a PMA for its device is the only one authorized to sell it in the United States. In some cases, a regulatory patent can provide more protection against competition than a patent issued by the Patent Office. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 520 (1988). A commentator also has used the term "non-patent patent." Bennett, *Patent Certification: Procedural Protection for the Pharmaceutical Innovator*, 40 Food Drug Cosm. L.J. 317, 317 (1985).

Lilly asserts that *de facto* patent extension can be avoided by moving FDA testing to a noninfringing venue abroad. Pet. Br. 31 n.21. Aside from the fact that such foreign testing would work a discrimination against smaller domestic device makers, the FDA may not approve an exclusively foreign clinical trial. See, Respondent's Brief in Opposition to Petitioner's Reapplication for an Order to Recall and Stay the Mandate, at p. 4 & App. E.

It is the last provision that must be construed in this case. The question before the Court is whether section 271(e)(1) exempts otherwise-infringing activities involving a medical device being tested for the purpose of submitting information to the FDA under the FD&C Act or whether the section is limited to drugs. Resolution of that question depends principally on the text of Section 271(e)(1) as enacted in 1984 and in effect at the time of trial, which provided:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

At that time, the simultaneously enacted section 156 provided patent term extension for all products subject to FDA regulatory delay other than the animal products excluded by the parenthetical in section 271(e)(1).

Assistance in understanding the statutory scheme is also provided by considering the Generic Animal Drug and Patent Term Restoration Act of 1988, Pub. L. No. 100-670, 102 Stat. 3971 (1988), ("1988 Amendments"), which amended the FD&C Act and 35 U.S.C. §§ 156 and 271(e)(1). The 1988 Amendments changed section 156 by explicitly making new animal drugs and veterinary biological products (other than those made by genetic engineering techniques) eligible for patent term extension. Simultaneously, section 271(e)(1) was amended to extend the testing exemption to those same animal products (new material italicized):

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) *which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques*) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

B. The Facts of this Case

In 1983, the predecessor-in-interest of petitioner Eli Lilly and Company ("Lilly") brought a patent infringement action against Medtronic to enjoin the testing to develop information on an implantable cardiac defibrillator for submission to the FDA.² Thirty-one devices involved in various stages of such testing were accused by Lilly as infringements.³

2. The patents allegedly infringed were U.S. Patent No. Re. 27,757 and No. 3,942,536. The '757 patent was to expire on October 26, 1988, but Lilly obtained a two-year extension of the patent under Section 156.

The notice required by Sup. Ct. R. 29.1 is provided in Respondent's Brief in Opposition to Petition for Writ of Certiorari at 1 n.1.

3. Two different Medtronic models were alleged to infringe by virtue of activities ranging from in-house laboratory tests, to in-house animal implants, to clinical implants in patients. Medtronic's Model 7215 Implantable Pacemaker Cardioverter Defibrillator ("PCD") is capable of automatically treating episodes of overly rapid heartbeat ("tachyarrhythmias"). The Model 7215 contains a microprocessor-controlled heart stimulator to deliver sequences of small pacemaker pulses or moderately sized "cardioverter" pulses to induce a return to normal heart rhythm without pain. If the arrhythmia degrades into a potentially fatal ventricular fibrillation, the device can deliver a high energy shock to terminate fibrillation. J. App. 66-67. Another Medtronic device alleged to infringe was the Model 7210. Both models were found at trial to infringe the '757 patent, but only the 7210 was found to infringe the '536 patent.

During pretrial proceedings, Medtronic moved to resolve the legal question whether 35 U.S.C. § 271(e)(1) shielded Medtronic from liability for infringement since Medtronic's devices were experimental, and the accused FDA testing activities had been undertaken to satisfy FDA compliance standards. The district court ruled that the section 271(e)(1) defense was "inapplicable to medical devices" and excluded any evidence at trial concerning Medtronic's defense under that statute. Pet. App. 19a. Hence, the record does not contain the evidence that would show that Medtronic's manufacture, use, and sale of the alleged infringing devices were "solely for uses reasonably related to the development and submission of information under" the FD&C Act within the meaning of section 271(e)(1). That issue has not been addressed or determined in this case.

The district court found the patents valid and infringed and entered an injunction against further infringement. Medtronic's appeal of that interlocutory injunction is the subject of this Court's review. The remainder of the case is not ripe for appeal since post trial motions on patent validity and infringement and other issues remain undecided by the district court. Hence, the basic issues of patent validity and infringement never have been reviewed, and Medtronic does not concede them here.

On appeal, the Federal Circuit reversed and held that section 271(e)(1) applies to medical devices.⁴ Pet. App. 1a. After finding both the statutory language and legislative history "ambiguous," the court of appeals concluded that Congress' purpose in enacting section

4. The court of appeals did not consider Medtronic's other bases for vacating the injunction. Hence, if this Court reverses, the case should be remanded for consideration of those other bases. Lilly's request that this injunction be reinstated forthwith is inappropriate.

271(e)(1) was best achieved by reading the statute to include medical devices. The Federal Circuit observed that section 271(e)(1) was contained in the same legislation, the DPC-PTR Act, that provided for patent extensions in 35 U.S.C. § 156, and that "the benefits of patent extension are not restricted to drugs, but extend to medical devices." *Id.* at 5a. The court found "[n]o persuasive reason . . . why Congress would create an exception with respect to [FDA-driven experimental] activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." *Id.* at 7a. Returning to the statutory language, the court held "that section 271(e)(1) allows a party to make, use, or sell *any type* of 'patented invention' if 'solely' for the restricted uses stated therein." *Id.*

Medtronic's latest version of a PCD, the Model 7216A which was developed after trial and is manufactured in Europe, is being clinically tested in the United States under an injunction modified after the court of appeals' ruling. Anticipating normal regulatory delays, the Model 7216A will not be approved by the FDA for general use until long after the '757 patent, as extended under 35 U.S.C. § 156, expires on October 26, 1990. J. App. 95, 99.

SUMMARY OF ARGUMENT

I. This case is governed by the plain language of 35 U.S.C. § 271(e)(1). Medtronic's PCDs were "patented invention[s]" and their testing was done under the FD&C Act which is "a Federal law which regulates . . . drugs." Both criteria of section 271(e)(1) are met.

"Patented invention" in section 271(e)(1) has an established broad and expansive meaning in the Patent

Act that encompasses all inventions including devices. The term cannot be restricted to human drug-related inventions by virtue of its own established meaning or the syntax in which it is used. Medtronic's PCD is irrefutably a "patented invention" as that term is used in section 271(e)(1).

Since Medtronic's PCDs were being tested under the FD&C Act, those activities were by definition "uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs." Congress used that phrase to refer to broad enactments including the FD&C Act and the Public Health Service Act ("PHS Act"). Even if "law which regulates . . . drugs" were construed (incorrectly) to refer to individual sections or subsections of the FD&C Act, rather than entire Acts, Medtronic still would prevail. The sections and subsections of the FD&C Act that regulate medical devices also regulate drugs. Therefore, regardless of the level at which the "law" specified in the section is approached, Medtronic's PCDs were tested under a "law which regulates . . . drugs."

II. This is also a case in which "only one of the permissible meanings" of section 271(e)(1)—Medtronic's—"produces a substantive effect that is compatible with the rest of the law." *United Savings Ass'n v. Timbers of Inwood Forest Assocs.*, 108 S. Ct. 626, 630 (1988). When Congress enacted the infringement exemption in section 271(e)(1), it simultaneously enacted patent term extension in section 156 which explicitly covers "medical devices." Section 271(e)(1) was intended to be co-extensive. When granting patent term extension in section 156, Congress made clear that "[t]here should be no other direct or indirect method of extending patent term." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 46

(1984) [hereinafter H.R. Rep. 98-857(I)]. The parallel amendments made to sections 156 and 271(e)(1) during the original legislative process and afterward by statutory amendment show that the two sections have consistently moved in lockstep to provide an exemption for testing of the same inventions as are eligible for patent extension.

III. Other aids to statutory interpretation also support Medtronic's position. Congress' dominant policy goal in enacting section 271(e)(1) was to foster early competition in medical technology consistent with preservation of necessary patent incentives for innovation. That goal is advanced as much by exempting medical device testing as by exempting drug testing.

Lilly's focus on Congressional statements concerning the statute's effect on the drug industry does not evidence a Congressional intent contrary to the plain meaning of the statutory text. Were such an argument valid, it could be applied to prove incorrectly that section 156 does not apply to medical devices; the legislative history of section 156 is as devoid of mention of devices as is that of section 271(e)(1). There is no indication that devices were to be excluded from the exemption of section 271(e)(1). Many decisions of this Court have shown that statutes can have effects not mentioned in their legislative history.

Finally, it is implausible that Congress meant the hazy line between drugs and medical devices, which the FDA must draw for regulatory purposes under the FD&C Act, to have significance in the very different field of patent infringement.

IV. Even if this Court determines that section 271(e)(1) is limited to drugs, it should affirm the judgment of the Federal Circuit. Section 271(e)(1) aside,

FDA-mandated experimentation is not patent infringement. The purposes of the FD&C Act and the Patent Act, as well as the general constitutional mandate enforced by this Court in a long line of cases that patents last only for a limited and definite time, strongly counsels against holding FDA-mandated testing to be patent infringement.

ARGUMENT

Section 271(e)(1) exempts the manufacture, use, or sale of a patented invention "solely for uses reasonably related to the development and submission of information under a *Federal law which regulates . . . drugs.*"⁵ (Emphasis added). Medtronic's devices were found to infringe Lilly's patents. Hence, by definition, Medtronic has been held to have made, used or sold a "patented invention." 35 U.S.C. § 271(a) (1982). The question presented for this Court to determine is whether the law under which Medtronic was testing the device, i.e., the FD&C Act, is a "Federal law which regulates . . . drugs."

Medtronic contends that the clause "which regulates . . . drugs" identifies the federal laws under which testing will be exempt, and not the kind of product on which testing may be done. Lilly asserts that section 271(e)(1) exempts testing of only the products mentioned at the end of the section, i.e., drugs. All of Lilly's arguments stem from the same fact, that the section does not refer to medical devices by name. The implication of Lilly's position is that Congress purposely created an inequality between drug and medical device patents by making both extendable, but exempting FDA testing only in the case

5. The 1984 version is the version of Section 271(e)(1) referred to throughout the brief unless expressly stated otherwise.

of drugs. There is no indication that Congress intended any such inequality. The statute should be read—in accordance with its unambiguous terms—to cover medical devices tested under the FD&C Act.

I. THE PLAIN LANGUAGE OF SECTION 271(e)(1) CREATES AN EXEMPTION FROM INFRINGEMENT FOR FDA TESTING OF MEDICAL DEVICES

Direct application of the plain language of section 271(e)(1) is conclusive in this case. *United States v. Ron Pair Enters., Inc.*, 109 S. Ct. 1026, 1030 (1989) (“where, as here, the statute’s language is plain, ‘the sole function of the courts is to enforce it according to its terms.’”); *Southeastern Community College v. Davis*, 442 U.S. 397, 405 (1979).

A. “Patented Invention” In Section 271(e)(1) Has The Same Broad Meaning As In 35 U.S.C. § 101 And Is Not Modified By The Words “Federal Law Which Regulates . . . Drugs”

The first portion of section 271(e)(1) states that a “patented invention” may be exempted from infringement if used as specified under a “law which regulates . . . drugs.” The phrase “patented invention,” on its face, broadly applies to *any* invention used for purposes exempted by the section. Lilly, however, thrusts the word “drugs” to the forefront and argues that “Federal law which regulates . . . drugs” modifies and restricts “patented invention” so that “invention” really means drug-related invention. Pet. Br. 21.

The argument is unfounded. Lilly’s contentions visit and revisit the word “drugs” in section 271(e)(1) without analysis of the text or the syntax of its use. The argument that “drugs” modifies and restricts “pat-

ented invention” (Pet. Br. 21) cannot survive careful scrutiny of how the word is used in the statute. It is an accepted principle of statutory construction that qualifying words refer only to the last antecedent.⁶ The ordinary rules of grammar and syntax must be applied to the task of statutory interpretation. *Ron Pair*, 109 S. Ct. at 1030-31.⁷

The established usage of “patented invention” throughout Title 35 and in section 271 also makes Lilly’s argument untenable. The term “patented invention” is defined by “broad general language” in the patent statute to include any new and useful “process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101 (1982). *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980).

Patent infringement in turn is defined in section 271(a) using that broad term: “whoever without authority makes, uses, or sells any patented invention, within the United States during the patent term therefor, infringes the patent.” Section 271(e)(1) provides that certain manufacture, use, or sale of a “patented invention” is not in-

6. Referential and qualifying words and phrases, where no contrary intention appears, refer solely to the last antecedent. The last antecedent is “the last word, phrase, or clause that can be made an antecedent without impairing the meaning of the sentence.” Thus a provision usually is construed to apply to the provision or clause immediately preceding it.

2 N. Singer, *Sutherland Statutory Construction* § 47.33 (4th ed. 1984) (footnotes omitted) [hereinafter *Sutherland*].

7. Congress is presumed to follow well-accepted rules of grammar absent an expressed intention to the contrary.

Certainly a legislature is not compelled by any superior force to obey dictionary definitions or the rules of grammar. Except where the contrary is clearly indicated, however, it is a fair assumption that the “authors” of legislation relied on conventional indicia of meaning in shaping their understanding. *Sutherland*, *supra* note 6, at § 45.14.

fringement. The term "patented invention" should not be construed more narrowly—to include only "human drug-related invention"—in subsection (e)(1) than it is in subsection (a). "[A] legislative body generally uses a particular word with a consistent meaning in a given context." *Mills Music, Inc. v. Snyder*, 469 U.S. 153, 165 n.31 (1985) (quoting *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972)). "[O]nly the most compelling evidence" should persuade the Court "that Congress intended the nearly identical language of . . . two provisions to have different meanings." *Communications Workers of America v. Beck*, 108 S. Ct. 2641, 2653 (1988); see also *Hillsboro Nat'l Bank v. Commissioner*, 460 U.S. 370, 402 (1983); *Roadway Express, Inc. v. Piper*, 447 U.S. 752, 760 (1980); *Sutherland*, *supra* note 6, at § 46.06.

When Congress used "patented invention," it provided section 271(e)(1) with the most explicit badge of broad scope that could be supplied by the Patent Act. 35 U.S.C. §§ 100-376 (1982 & Supp. I 1983 - Supp. V 1987), as amended by Pub. L. No. 100-670, 102 Stat. 3971 (1988). This Court has rejected attempts to avoid the statutory definition of section 101. *Parker v. Flook*, 437 U.S. 584, 590 (1978) ("patentable subject matter under § 101 is not 'like a nose of wax which may be turned and twisted in any direction'").

"Absent legislative intent to the contrary, or other evidence of a different meaning, legal terms in a statute are presumed to have been used in their legal sense." *Sutherland*, *supra* note 6, at § 47.30 (footnotes omitted). Congress chose a broad statutorily defined term, then modified it with a highly specific adjacent parenthetical. It defies statutory construction principles to suppose Congress also intended the remote word "drugs" to modify

"patented invention" in order to make it reflect only a portion of its accepted statutory meaning.

B. The Federal Food, Drug, And Cosmetic Act Is "A Federal Law Which Regulates The Manufacture, Use, Or Sale Of Drugs"

1. The Language Of Section 271(e)(1) Is Unambiguous

The plain language of section 271(e)(1) exempts the testing of patented inventions under any "Federal law which regulates . . . drugs." The FD&C Act is such a law. It provides the authority for the FDA to prescribe rigorous testing regimes for drugs and medical devices. Another Federal law which regulates drugs is the PHS Act.⁸ See 35 U.S.C. § 156(f)(1)(b) and (f)(2).

Having established that medical devices are within the ambit of the broad phrase "patented invention," it is now apparent that the second condition of the statute is fulfilled by FDA testing of medical devices. All such testing is conducted under statutory provisions of the FD&C Act, a law which regulates, among other things, the manufacture, use, and sale of drugs. Although Lilly does not and cannot dispute those facts, it offers a number of arguments that do not address the text of section 271(e)(1) apart from its reference to "drugs."

Section 271(e)(1) is argued to be limited to drugs because drugs are the only products mentioned by name. Pet. Br. 16. According to Lilly, Congress' reference to "Federal law which regulates . . . drugs" does not specify

8. The PHS Act gives the FDA statutory authority to regulate human biological products, which are a subset of human drugs having a biological as opposed to a chemical origin. 42 U.S.C. §§ 262-63; 21 C.F.R. § 600 ("Authority" clause); § 600.3(h). That authority is not given by the FD&C Act. See 21 U.S.C. § 392(b) (1982).

those federal laws under which testing would be exempt, but rather defines the kinds of products that could be the subject of exempted activities. Pet. Br. 21. That conclusion is in hopeless conflict with the words of the statute.

Lilly's assertion (Pet. Br. 16) that Congress could not have meant the phrase "Federal law which regulates . . . drugs" to mean the FD&C Act, because Congress would have just referred to that Act by name, is wrong because it incorrectly assumes that the FD&C Act was the only statute that Congress intended to describe in the quoted passage. But the human biologicals regulated under the PHS Act form a subset of "human pharmaceuticals" (note 8, *supra*) that even Lilly concedes can be tested under section 271(e)(1). Pet. Br. 24. Thus, it is not "odd" (Pet. Br. 10-11) that Congress chose the language it used in section 271(e)(1). The language was intended to describe several laws that Congress had expressly referred to in sections 156(f)(1) and (2) to define *all* products, i.e., drugs, devices and food and color additives," which could trigger patent extension. The chosen language of section 271(e)(1) efficiently embraces the statutes requiring testing and elsewhere acknowledged in the DPC-PTR Act.

Although presented under the banner of "plain language," Lilly's argument fails to respect the language of the statute. If the "Federal law" clause is such an awkward way to describe the FD&C and PHS Acts that this Court should search for an alternative meaning, Lilly proposes no alternative that is faithful to the text.

9. Lilly is incorrect that the products subject to patent extension are defined only in parts (A) and (B) of section 156(f)(1). Section 156(f)(2) which identifies the FD&C Act and the PHS Act is essential to identify the "products" which can result in patent extension.

The statute refers to "a Federal law which regulates . . . drugs," but Lilly would transform the supposed awkwardness of that phrase into a license to ignore the syntax of the statute and to read it as not referring to a set of laws at all.¹⁰ In fact, the language efficiently describes the set of federal laws under which the testing must take place (those that regulate drugs), rather than the set of products (drugs) that must be tested under some federal law.¹¹

Because section 271(e)(1) unambiguously refers to the type of "law" under which testing must take place, Lilly makes an isolated argument (Pet. Br. 10) that "law which regulates . . . drugs" means only section 355 of the FD&C Act. 21 U.S.C. § 355 (1982 & Supp. V 1987). That section defines the pre-market approval testing regimen for human drugs. The argument cannot be reconciled with the terms of section 271(e)(1).

10. The different definitions of drugs and devices in the FD&C Act (Pet. Br. 14) are irrelevant because the same law, the FD&C Act, regulates both. Courts "must give effect, if possible, to every word of the statute." *Bowsher v. Merck & Co.*, 460 U.S. 824, 833 (1983). The "operative language" (Pet. Br. 21) is *every word* of the statute, not the single word "drugs." The cases cited by Lilly at Pet. Br. 16 are inapposite. The construction advocated by Medtronic does not ascribe similar meanings to the different phrases in section 271(e)(1) since the "Federal law" clause encompasses laws in addition to the FD&C Act.

11. Contemporaneously with its original passage, one commentator noted that the last clause was broader than just the FD&C Act:

Section [271(e)(1)] provides that it shall not be an act of infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information *under a federal law which regulates the manufacture, use or sale of drugs. Not under the Food, Drug and Cosmetic Act or not solely to gain an ANDA or NDA, but under any federal law which regulates the manufacture, sale or use of a drug.*

Krulwich, *Statutory Reversal of Roche v. Bolar: What You See Is Only the Beginning of What You Get*, 40 Food Drug Cosm. L.J. 519, 524 (1985) (emphasis in original).

Section 271(e)(1) as originally passed contained a parenthetical excluding "new animal *drug[s]*" and "veterinary biological product[s]" from the exemption. But animal *drugs* are not regulated under section 355 of the FD&C Act but rather under section 360b. 21 U.S.C. § 360b (1982 & Supp. V 1987), *as amended* by Pub. L. No. 100-670, 102 Stat. 3971 (1988). If "law" meant only section 355, there would have been no need to use the parenthetical to exclude those products from section 271(e)(1).

Lilly also argues that the reference to "law" in section 271(e)(1) designates sections and not Acts because Congress would not use "shorthand" to designate the entire FD&C Act as a "law which regulates . . . drugs." Pet. Br. 15. But there is no reason why Congress would have been so obscure as to use the general language of section 271(e)(1) to identify one specific section among the many sections of the FD&C Act that regulate drugs. It is far more sensible to read the broad phrase "Federal law which regulates . . . drugs" to mean entire enactments such as the FD&C Act rather than *one* of its many drug-related sections.¹²

12. Other legislation referring to "Federal law" has been construed to refer to overall statutory enactments. For example, under 15 U.S.C. § 2608(a) (1988), the EPA may allow another agency to handle a toxic substance if "risk [from the toxic substance] may be prevented or reduced to a sufficient extent by action taken *under a Federal law* not administered by the [EPA]." (Emphasis added). The Ninth Circuit recently interpreted that section and equated "Federal laws" with broad enactments: "The legislative history cited by Alyeska indicates that Congress was concerned about laws administered by other regulatory agencies rather than forcing the EPA to 'pigeonhole' investigations under particular statutes." *EPA v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 447 (9th Cir. 1988). See also *Environmental Defense Fund v. EPA*, 598 F.2d 62, 77 (D.C. Cir. 1978) ("Federal law" considered to encompass other statutes and Acts).

Statutory construction must begin with the language to which a majority of the members of both Houses of Congress could agree, because the legislative purpose is assumed to be expressed through the ordinary meaning of the words used.

In cases of statutory construction we begin, of course, with the language of the statute. *Southeastern Community College v. Davis*, 442 U.S. 397, 405 (1979). And "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." *Perrin v. United States*, 444 U.S. 37, 42 (1979). We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

Diamond, 447 U.S. at 308.

Again and again, this Court has sounded the same theme: the most reliable method of carrying out the intent of Congress is to give careful attention to the statutory text, and not to assumptions about congressional "intent" divorced from statutory text.¹³ Careful attention to the

13. See, e.g., *Pavelic & Leflore v. Marvel Entertainment Group*, 58 U.S.L.W. 4038, 4039 (1989) ("Our task is to apply the text, not to improve upon it."); *Northbrook Nat'l Ins. Co. v. Brewer*, 110 S. Ct. 297, 301 (1989) ("We cannot doubt that Congress meant what it said."); *Bourjaily v. United States*, 483 U.S. 171, 178 (1987) ("It would be extraordinary to require legislative history to *confirm* the plain meaning of" a statute.); *United States v. James*, 478 U.S. 597, 604 (1986) ("We assume that the legislative purpose is expressed by the ordinary meaning of the words used."); *Mills Music*, 469 U.S. at 164 ("In construing a federal statute it is appropriate to assume that the ordinary meaning of the language that Congress employed 'accurately expresses the legislative purpose.'"); *Garcia v. United States*, 469 U.S. 70, 78 (1985) ("We are not willing to narrow the plain meaning of . . . a . . . statute on the basis of a gestalt judgment as to what Congress probably intended."); *United States v. Locke*, 471 U.S. 84, 95-96 (1985) ("[T]hat Congressmen typically vote on the language of a bill, generally requires us to assume that the 'legislative purpose is expressed by the ordinary meaning of the words used.'");

language of section 271(e)(1) can produce only one result:¹⁴ "law which regulates . . . drugs" identifies a set of laws that includes the FD&C Act. Medtronic's medical devices were tested under the FD&C Act, and they therefore come within the terms of the statute.¹⁵

2. The 1988 Amendments Confirm That Congress Used The "Law Which Regulates . . ." Construction To Identify Entire Acts Of Congress

The 1988 Amendments conclusively establish that "Federal law which regulates . . . drugs" was meant to include the entire FD&C Act and PHS Act. Those Amendments broadened the exemption of section 271(e)(1) by amending the "law which regulates" clause in section 271(e)(1) to refer to "law which regulates . . . drugs or veterinary biological products." Lilly argues that the addition of "veterinary biological products" is evidence that Congress

New England Power Co. v. New Hampshire, 455 U.S. 331, 343 (1982) (Courts have no authority to rewrite legislation based on "mere speculation as to what Congress 'probably had in mind.'").

14. Senator Metzenbaum's admonition to those who would be construing the DPC-PTR Act is enlightening:

[T]here are many people asking what this bill is all about; what it means; how do you interpret it. Let me say, for one, that I interpret it in only one manner. Nobody can change the language of the legislation. It speaks for itself. So notwithstanding anybody who may feel that they can interpret the language of this legislation in one way or another, I want the courts to understand that the legislation speaks for itself and the interpretation which anyone may make on the floor does not really add anything to that interpretation.

Text of S. 2926 and Floor Remarks, *reprinted in* 28 Pat. Trademark & Copyright J. (BNA) 435, 447 (1984).

15. Judge Newman termed the panel's decision "judicial legislation" (Pet. App. 12a) while advancing an all too apparent misreading of the statute. Pet. App. 10a. Section 271(e)(1) is not "limited to the 'manufacture use or sale of drugs'" as Judge Newman suggested. *Id.* Neither Judge Newman nor Lilly ever squarely confronts the fact that "drugs" modifies "law" and nothing else.

named in section 271(e)(1) all the products that it wished to make eligible for exemption under that statute. Pet. Br. 14 n.8. In fact, Congress did nothing of the kind.

Interstate commerce in veterinary biological products is regulated under the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-58 (1982 & Supp. I 1983 - Supp. V 1987); *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). Thus, the addition of "veterinary biological products" to the "law which regulates" clause means that testing *under a law that regulates veterinary biological products* (the Virus-Serum-Toxin Act) is exempt. The 1988 Amendments were not Congressional attempts to name all exempt products in section 271(e)(1).

Furthermore, the amendments disprove Lilly's assertion that the "law which regulates" clause refers to (unspecified) discrete individual sections of Acts of Congress. There can be no doubt that the reference to "law which regulates . . . veterinary biological products" in the amended section 271(e)(1) refers to the entire Virus-Serum-Toxin Act.¹⁶ In the simultaneous parallel amendments to the patent extension statute, 35 U.S.C. § 156, Congress made several specific references to products and applications "subject to" or "under" "the Virus-Serum-Toxin Act." See 35 U.S.C. § 156(d)(2)(A)(i), (d)(2)(B)(i), (g)(5)(B)(i), (g)(5)(B)(ii). Nonetheless, Congress chose the more generic expression in section 271(e)(1).

16. The Virus-Serum-Toxin Act, is the same as "the Act of March 4, 1913" which appears in the parenthetical of section 271(e)(1). The fact that Congress identified that Act in an early part of the section, and referred to the same law as one which "regulates . . . veterinary biological products" at the end, further refutes Lilly's argument that Congress' cite of the FD&C Act at one part of the section would compel repetition of that cite to identify the "law."

3. The Sections And Subsections Of The FD&C Act That Regulate Drugs Also Regulate Devices

Medtronic has demonstrated that Congress used the phrase "law which regulates . . . drugs or veterinary biological products" in section 271(e)(1) to designate broad enactments. But even if the word "law" should mean an individual section rather than an entire Act (Pet. Br. 10), Medtronic still would prevail. The structure of the FD&C Act does not, for the most part, contain discrete and segregable "device provisions" as Lilly suggests. Pet. Br. 15. The statement that "[d]rugs and devices are regulated under entirely different statutory provisions" (Pet. Br. 14-15) is true only in one respect: sections 355 and 360 outline the respective testing requirements for new drugs and new medical devices. But the general prohibition against introducing a new drug or device into commerce without meeting those testing requirements, and thus their "regulation," is contained in a single section—section 331. 21 U.S.C. § 331 (1982 & Supp. V 1987). "The heart of the enforcement provisions of the FD&C Act is [Section 331], which enumerates the acts prohibited by the statute." R. Merrill & P. Hutt, *Food and Drug Law* 661 (1980).

Both drugs and medical devices are regulated by section 331 of the FD&C Act. It contains subsections that vary in scope and cut across distinctions among food, drugs, devices and cosmetics. The section directs the reader to other sections of the Act, which in turn detail the procedural requirements that must be met to qualify different products and thus overcome the prohibition against introducing them into commerce.

For illustration, consider the following subsections of section 331. Subsection 331(a) prohibits placing in

interstate commerce "any food, drug, device, or cosmetic that is adulterated or misbranded." Subsection 331(d) prohibits placing any article in interstate commerce in violation of section 344, which provides food regulation, or section 355, which provides the basic regulation of new drugs. Subsection 331(e) prohibits the failure to maintain and permit access to certain records required to be kept under subsections 355(i) or (j), which regulate clinical test reports for new drugs, under subsections 360b(j), (l) or (m), which deal with new animal drugs, or under subsection 360e(f), which is directed to developing protocols and reports on medical devices. Subsection 331(p) prohibits the failure to register or provide certain information in accordance with section 360 and specific subsections of section 360, which provide the overall registration regulation for both drugs and medical devices.

The subsections of section 331 that regulate devices also regulate drugs. Subsection 331(p) requires submission of information on drugs under subsection 360(j). It also requires submission of information under subsection 360(k), which specifies the tests that must be submitted before introduction of devices into interstate commerce. Subsection 331(e) regulates and requires the development and submission of information and does so for human drugs, animal drugs, and medical devices. Medtronic's development and submission of information was done in compliance with subsections 331(p) and 331(e), which, as part of section 331, "regulate[] the manufacture, use, or sale of drugs."

No matter how narrowly Lilly tries to read "Federal law," medical device testing is done under a "Federal law which regulates . . . drugs." Test information on medical devices is developed and submitted under an *Act* of Congress that regulates drugs, the FD&C Act; a *section*

that regulates drugs, section 331; and *subsections* that regulate drugs, subsections 331(p) and 331(e). It follows, then, that the development and submission of information on medical devices qualifies for the protection of section 271(e)(1) as much as the development and submission of information concerning drugs. Lilly's view that devices are excluded from section 271(e)(1) would require parsing sentences and even clauses within subsections to determine the activity to which the exemption applies, a process that Congress' language does not contemplate. The compulsion of the statutory language should end the matter. *Ron Pair*, 109 S. Ct. at 1030.

II. THE PLAIN MEANING IS SUPPORTED BY THE STATUTORY CONTEXT OF THE LEGISLATIVE PACKAGE CONTAINING SECTION 271(e)(1)

The analysis of the statutory language advanced above is dispositive. It is reinforced and illuminated by a review of the companion provisions in Title II of the DPC-PTR Act, which utterly contradict Lilly's arguments on the legislative intent.

As discussed at page 2, *supra*, the DPC-PTR Act effected two major amendments to the patent statute. Section 156 made patent extensions available to product or process patentees who experienced delay in commercializing a "human drug product"¹⁷ or "[a]ny medical device, food additive or color additive subject to regulation under the [FD&C Act]." In the context of that patent term extension, Congress simultaneously created the exemption in section 271(e)(1) for all "patented inventions" (except for animal drugs and veterinary biological products) when employed "for uses reasonably

17. Under section 156 human drug products corresponded to "a new drug, antibiotic drug, or human biological product" as defined in the FD&C Act and the PHS Act. See 35 U.S.C. § 156(f)(2)(A).

related to the development and submission of information under a Federal law which regulates . . . drugs."

Because "[s]tatutory construction . . . is a holistic endeavor," the meaning of a statute should be regarded as clear when "only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *United Savings*, 108 S. Ct. at 630. Construing section 271(e)(1) in the context of the DPC-PTR Act reveals an unmistakable symmetry between sections 156 and 271(e)(1). Because medical devices are covered by section 156, they should be covered by section 271(e)(1) as well.

A. Congress Intended That Sections 156 And 271(e)(1) Have The Same Scope

The objectives of the DPC-PTR Act were to remedy the negative effects of FDA regulatory delays on achievement of the goals of the patent system. Those goals were to stimulate innovation by rewarding inventors with "the right to be free from competition in the practice of the invention" for a limited time, *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1944), and to make the invention immediately available to the public upon the patent's expiration.¹⁸

Prior to passage of the DPC-PTR Act, FDA regulatory delays and the decision in *Roché Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 8, 8 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), combined to produce both *de facto* reductions and *de facto* extensions in patent

18. An exclusive enjoyment is guaranteed [the inventor] for seventeen years, but upon expiration of that period, the knowledge of the invention inures to the people who are thus enabled without restriction to practice it and profit by its use.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 109 S. Ct. 971, 977 (1989) (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87 (1933)).

terms. The effects of regulatory delay, therefore, were to shift the effective patent term in time. But the intrusion of the regulatory process made the beginning and end of the effective term unpredictable and indefinite.

Sections 156 and 271(e) were intended to strike a balance between the patentee's *de facto* loss of patent term and the *de facto* extension of that term that resulted from FDA regulatory delay. The remedy chosen by Congress was to grant patentees a definite extension of their patent term up to five years upon a proper showing. In turn, Congress chose to eliminate any *de facto* extension of patent term.

The House Energy and Commerce Committee made it clear that section 271(e)(1) was designed to eliminate those *de facto* extensions:

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. *That limited time should be a definite time and, thereafter, immediate competition should be encouraged.*

* * *

[E]xperimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but *prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.*

* * *

[The provisions of section 156] permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. 98-857(I), *supra* p. 7, at 45-46 (emphasis added).

Those statements of Congressional intent are totally inconsistent with the notion that Congress wanted to limit the exemption of section 271(e)(1) to drugs. Without doubt, Congress intended broadly to substitute the definite patent extension provided by section 156 for the *de facto* extension which results if FDA-mandated testing of those products can be deemed patent infringement. To hold otherwise would be to postulate a Congressional objective to prefer medical devices and other FDA-regulated inventions to drug inventions. Section 271(e)(1) was designed to preclude indefinite *de facto* extensions for *all* products entitled to statutory extensions under section 156.¹⁹ To accomplish that purpose the scope of products affected by section 271(e)(1) must be the same as those affected by section 156.²⁰

A Congressional grant of term extension to devices without an accompanying exemption would be inconsistent with the marked congressional restraint otherwise evident during consideration of the DPC-PTR Act. For example, Congress decided to limit the maximum term of a possible extension to five years, which was significantly less than the average ten-year regulatory compliance period for the average new drug invention. 130

19. The importance of that objective was emphasized by one commentator involved with the legislative process: "Congressman Waxman took the position that, while a pioneer is entitled to his patent, perhaps even extended, when the patent expires, competition should begin, not delayed by the need to perform studies to satisfy the FDA." Lourie, *Patent Term Restoration*, 66 J. Pat. Off. Soc'y 526, 534-35 (1984) [hereinafter Lourie].

20. The Federal Circuit recognized that section 271(e) should have the same scope as section 156 so as to preclude any one product from receiving both direct and indirect extensions. The court stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." *Eli Lilly & Co. v. Medtronic, Inc.*, Pet. App. 7a (emphasis added).

Cong. Rec. H8706 (daily ed. Aug. 8, 1984). That cautious legislative approach to term extension simply does not harmonize with a legislative intent to grant medical device inventions a preferred status vis-à-vis drug inventions.

As the frontiers of medical technology expand, the treatment of life-threatening diseases probably will involve the development of more complex and risk-laden devices. It is logical to assume that the level of FDA scrutiny will increase. If the "secondary patent" or "regulatory patent" is allowed to exist for medical devices—contrary to Congress' expressed intent to eliminate "direct and indirect" means of patent extension other than section 156—it will become an even greater impediment to market entry in the future.

In the DPC-PTR Act, Congress granted patent term extension rights to human drugs and biologicals, medical devices, and food and color additives. To fulfill its objective of eliminating indirect patent term extension for those products, it was required in section 271(e)(1) to exempt regulatory testing of those products from infringement.²¹ Maintenance of the internal balance within the DPC-PTR Act requires that the exemption apply to medical devices.

B. The Legislative Evolution Of Section 271(e)(1) Shows That Congress Consistently Maintained Congruency With Section 156

When the earliest version of the DPC-PTR Act was reported out of the House Subcommittee on Health and

21. Section 271(e)(1) will have little effect on food and color additives or cosmetics. Cosmetics do not require premarket approval testing. Additives are tested typically by the first manufacturer to establish regulations for their use. 21 U.S.C. § 348(b) (1982). Subsequent competitors are required only to satisfy those regulations, § 348(a)(2) (1982), and would not face a significant delay to market from a "regulatory patent" after patent expiration.

the Environment, the bill provided for term extension for inventions subject to FDA regulation.²² H.R. Rep. 98-857(I), *supra* p. 7, at 16-17, 37-47. Simultaneously, the companion FDA-testing exemption was available for any patented invention provided the use was "reasonably related to the development and submission of information under a federal law which regulates . . . drugs." *Innovation and Patent Law Reform: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 98th Cong., 2d Sess. 630-49 (1984) [hereinafter *Innovation Hearings*].

Before the final amendments to the DPC-PTR Act in September 1984, Congress decided to address patent extensions for animal drugs and veterinary biological products in the legislative subcommittee that deals with agricultural subjects.²³ To uncouple the animal products from the pending DPC-PTR Act, Congress expressly eliminated animal drugs and veterinary biological products from the list of products in section 156 that could trigger patent term extension. Compare text of H.R. 3605 found in *Id.* at 600-49 with text of H.R. 3605 found at 130 Cong. Rec. H9150 (daily ed. Sept. 6, 1984). Patent term extension then remained available only for human drugs, including human biological products, medical devices, and food and color additives. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 7 (1984) [hereinafter H.R. Rep. 98-857(II)]. Simultaneously, Congress inserted the parenthetical exception after "patented invention" in the pending section 271(e)(1). S. 2926, 98th Cong., 2d Sess., 130 Cong. Rec. S10512 (daily ed. Aug. 10, 1984).

22. Patent term extension at this stage was proposed for human and animal drugs (including human and animal biological products), medical devices, and food and color additives.

23. Lourie, *supra* note 19, at 540.

After 1984, Congress sought to maintain the congruency. In 1986, a proposed bill sought to amend section 156 to provide term extension for all animal drugs and veterinary biological products. At that point, the proposed amendment to section 271(e)(1) would have made the same products exempt by deleting the entire parenthetical expression in that section. S. Rep. No. 448, 99th Cong., 2d Sess. 10-11 (1986). But the genetic engineering industry objected and sought to exclude genetic engineering inventions from the exemption of section 271(e)(1). The result was that in the 1988 Amendments the total congruency was preserved. The exemption for genetically engineered animal drugs and veterinary biologicals was withdrawn from section 271(e)(1) and patent term extension for the same products simultaneously was removed from section 156. 134 Cong. Rec. H9785 (daily ed. Oct. 6, 1988) (statement of Rep. Waxman).

Those complementary actions provide an unmistakable signal that section 156 and section 271(e)(1) were designed to be congruent in scope. Had Congress intended to exclude devices from section 271(e)(1), it would have expressly added medical devices to the exclusionary parenthetical. The inevitable conclusion is that the legislative intent was to include devices in section 271(e)(1).

C. Section 271(e)(1), Unlike Section 271(e)(2), Is Not Limited To Generic Drug Applications

Section 271(e)(1)—at issue here—defines certain acts *not* to be patent infringement, whereas section 271(e)(2) states that the submission of certain kinds of FDA applications *is* patent infringement. Because section 271(e)(2) refers to certain kinds of applications that can be submitted only for generic drugs, Lilly and its *amici* assert

that it must follow that section 271(e)(1) applies only to generic drugs. There is, however, no basis for that inference.

Section 271(e)(2) prohibits the mere filing of an application for expedited approval via ANDA or "paper" NDA procedures—procedures that are available only for generic drugs²⁴—with an intent to commercialize a patented product before the expiration of the patent. But filing an application to test a pioneer drug under full NDA procedures is not defined as an act of infringement in section 271(e)(2). Yet Lilly agrees that section 271(e)(1) expressly exempts the testing of pioneer drugs. *See* Pet. Br. 30 n.20. Thus, section 271(e)(1) undeniably is broader than section 271(e)(2), and section 271(e)(2) provides no basis for asserting that section 271(e)(1) is limited to bioequivalency testing of generic drugs.

In the medical device arena there are no provisions, comparable to those for drugs, for abbreviated safety and efficacy testing of medical devices in the class of implantable defibrillators. 21 U.S.C. 360c(a)(1)(C) (1982). Thus, just as there was no need to provide patentees special protection in section 271(e)(2) for pioneer drug testing, there was no need to provide protection in section 271(e)(2) for complete testing of medical devices such as the PCD which requires the most rigorous testing.

24. The ANDA (abbreviated new drug application) and paper NDA (new drug application) procedures involve shortened and less onerous test requirements than the requirements to qualify a new drug under full NDA procedures. *See* 21 U.S.C. §§ 355(b)(2) and (j). "Pioneer" drugs are new compositions that must pass the most rigorous approval protocols under NDA procedures. Generic drugs are usually chemical copies of a pioneer drug composition; they emerge in large drug markets when the pioneer drug goes "off-patent." The abbreviated ANDA or paper NDA procedures are available to generic manufacturers since there has been significant experience with the pioneer drug.

Lilly's argument that subsection (e)(2) limits subsection (e)(1) has no merit.

D. Section 271(e)(1) Is Not Limited To Generic Bioequivalency Testing

The suggestion that section 271(e)(1) is limited to generic bioequivalency testing is insupportable. Pet. Br. 29. The express language of section 271(e)(1) exempts more than generic bioequivalency testing. Lilly and its *amici* concede that pioneer drug testing is exempted. Pet. Br. 30 n.20; Pfizer Br. 5 n.4; Bristol Myers Br. 16. Use of a patented process reasonably related to preparing or administering a new pioneer drug also is exempt. Most significantly, the language of section 271(e)(1) clearly would exempt the use of a patented device such as an atomizer, if its use is reasonably related to the clinical testing of a generic or new inhalant drug, for example. The exemption of section 271(e)(1) simply is not restricted merely to patented drug inventions used in generic bioequivalency testing but embraces the entire scope of useful patented inventions.²⁵

That conclusion is supported by a detailed analysis of the scope of section 271(e)(1). See Wheaton, *Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Cath. U.L. Rev. 433 (1986). Professor Wheaton determined that section 271(e)(1) is not

limited to the compilation of information necessary to submit an ANDA, instead, the statute refers to "any Federal law" regulating the manufacture, use,

25. By the 1988 Amendments, section 271(e)(1) was modified to preclude from the infringement exemption the use of patented genetic engineering processes if used in connection with testing animal drugs. That is was necessary to specifically exclude this one type of patented process from the infringement exemption shows clearly that use of such patented processes for human drugs, as well as use of all non-genetic patented processes, are left within the infringement exemption.

or sale of drugs. Thus, as the provision is written, it would not be an act of infringement for a manufacturer to conduct tests needed to submit a paper NDA for a generic copy of the new drug, or a full NDA for a use or dosage form not already approved in the pioneer drug's NDA.

Id. at 462. The part of the DPC-PTR Act that matured into section 271(e)(1) never was restricted to bioequivalency testing of generic drugs, or to drugs at all.²⁶

III. EXTRINSIC AIDS TO STATUTORY CONSTRUCTION SUPPORT MEDTRONIC'S PLAIN MEANING INTERPRETATION

A. The Public Policy Goals Chosen By Congress Are Best Furthered By According Section 271(e)(1) Its Plain Meaning

The DPC-PTR Act implements specific policy choices made by Congress to encourage innovation and competition in FDA-regulated products. To stimulate innovation, Congress gave patentees of FDA-regulated products patent term extension to restore a period of market exclusivity lost because of FDA delays. To promote free competition upon the patent's expiration, Congress gave competitors the right to do necessary FDA testing during

26. Lilly quotes out of context (Pet. Br. 32) an isolated statement from the legislative history that might seem to suggest that bioequivalency testing was the "only activity" permitted under Section 271(e)(1). See Sec. III.B, *infra*. The cited comment was made in response to a proposed amendment by Representative Moorhead that challenged the constitutionality of the section 271(e)(1) exemption on the ground that it was an improper "taking" of property. Representative Moorhead had sought to introduce a waiver provision in the pending patent restoration provision under which the patentee would make a limited waiver permitting generic bioequivalency testing if term extension were sought. The Congressional statement suggesting that "only" bioequivalency testing is permitted was a response to that amendment and represents an understandable lapse in the context of rejecting the "taking" argument. It does not represent the kind of legislative history that can overcome the clearly contrary terms of a statute.

the patent term. Those choices support the construction that section 271(e)(1) exempts testing necessary to secure FDA approval of devices. See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980) (policy choices attributable to Congress can be determinative of statutory construction).

Section 271(e)(1) reflects the policy decision by Congress that public health concerns outweigh a private patentee's interest in preventing the start of FDA testing until the patent expires. Even though generic drugs are merely less expensive copies of existing and available drugs, Congress believed that their prompt introduction upon patent expiration warranted the enactment of section 271(e)(1). Lifesaving devices such as implantable defibrillators face regulatory barriers to market entry as formidable as those faced by drugs. *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 596 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986). The congressional choice in favor of public health is advanced by making device testing exempt in accordance with the plain language of section 271(e)(1) so that improved lifesaving devices become available to the public immediately after a patent's term.

Exempting medical device testing under section 271(e)(1) also spurs innovation, an additional goal of Congress in passing the DPC-PTR Act. Unlike generic drug companies, competitors in the medical device industry succeed by providing an improved product, not merely a cheaper one. The pharmacological efficacy of a drug may remain near optimal through the entire patent term. In contrast, most device inventions undergo significant improvement by the end of patent term.²⁷ As device patents

27. Evidence at trial established that Medtronic's Model 7215 contained features "ideal" for an implantable device designed to

approach the end of their term, the availability of the section 271(e)(1) exemption will advance medical knowledge, benefit public health, and spur innovation to provide superior devices soon after expiration of a patent that otherwise would be broad enough to preclude such development.²⁸ *Orphan Drug Amendments of 1987: Hearings on H.R. 3349 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 2d Sess. 24 (1987) (statement of Commissioner of the FDA) ("For [worthwhile] devices, the public health would not be well served if we were to block innovation through the application of an exclusivity provision that limited even minor improvements.") [hereinafter *Orphan Drug Hearings*]. If the exclusionary effects of the "regulatory patent" can preserve the patentee's exclusivity beyond the date of patent expiration, there is an affirmative disincentive to improve upon the patented device. Competitors will devote resources to areas where there is less impediment to free competition.

Congress did not subordinate section 271(e)(1) to the patentee's interests by tailoring the section to exempt only uses having no effect on the patentee's market. Pet. Br. 30. Although the section exempts typical generic bioequivalency drug testing in which the patented drug is

treat tachyarrhythmias. J. App. 53-54. Whereas Lilly has had an implantable defibrillator with pacing capabilities under development since prior to trial in March, 1988 (J. App. 58), as of this writing, their commercial device offers only high energy shock therapy. J. App. 69-70. There clearly exist patients for which that traumatic high energy shock therapy is inappropriate. J. App. 50, 65, 71, 75-78. The injunction in this case has affirmatively precluded some patients in the United States from obtaining the best available therapy. J. App. 82-83.

28. For example, a device such as the Medtronic PCD strives to use the latest in a spectrum of technical disciplines such as microelectronics, microprocessors, and battery technology.

given to healthy volunteers who would not otherwise purchase it, the section also plainly exempts bioequivalency testing when the drug is given to individuals in the patentee's target population because the drug has toxic side effects. Bristol Myers Br. 15 n.21. More significantly, the testing of a new drug on potential patients of the patentee also is permitted. Pet. Br. 30 n.20.

The dominant Congressional purpose was to permit testing during the patent term of the latest medical technology on the limited basis allowed by the FDA so that patent expiration could signal the onset of active competition. H.R. Rep. 98-857(1), *supra* p. 7, at 45-46. In passing the DPC-PTR Act, Congress made the policy judgment that such minor incursion on a patentee's right to exclude and, in a few instances, on its market exclusivity, would not deter innovation since the patentee would receive the balancing benefit of patent term extension.²⁹

29. A major device manufacturer with the potential to develop a new device and therapy can obtain a patent extendable to twenty-two years. It simply is not credible that the prospect of some "competition" from others conducting clinical tests near the end of patent term would discourage such innovation. Lilly furnishes a misleading example of an expensive CAT-scan device which would seriously damage the patentee's market if sales for FDA testing were exempt from infringement. Pet. Br. 30. But CAT-scan devices are Class II medical devices and normally do not undergo the type of testing that would enable a competitor to avail itself of the testing exemption of section 271(e)(1). See 21 C.F.R. §§ 892.1740 & 1750; 21 U.S.C. § 360c(a)(1)(B). In fact over 90% of medical devices brought to market do not require testing. See, e.g., Kahan, *FDA Regulations of Drug-Device Combinations*, Medical Device and Drug Industry, 58, 60 (Oct. 1989) [hereinafter Kahan].

Concerns that Investigational Review Boards ("IRBs") might be used by manufacturers as a subterfuge (Neuromedical Br. 5) to gain commercial advantage are unfounded. The composition and procedures of IRBs are strictly defined. 21 C.F.R. §§ 56.107-09, 111. Further, testing of any device significantly benefitted by section 271(e)(1) (21 C.F.R. § 812.3(m) & 21 U.S.C. § 360c(a)(1)(C)) is supervised by both the FDA and each IRB. 21 C.F.R. §§ 812.66, 812.30(a).

B. The Legislative History Supports The Conclusion That Congress Chose To Exempt All Products That Undergo FDA Testing

In enacting section 271(e)(1), Congress wanted to promote free competition in FDA-regulated products immediately upon patent expiration.

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. *That limited time should be a definite time and, thereafter, immediate competition should be encouraged.*

* * *

[The provisions of section 156] permit the extension of the term of a patent [on certain FDA-regulated products] for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. 98-857(1), *supra* p. 7, at 45-46 (emphasis added).

Congressional statements discussing the projected effects of the legislation on the drug industry (Pet. Br. 22-23) do not evidence a narrower objective. This Court has observed that "congressional discussion [which] focused on the needs of female members of the work force rather than spouses of male employees . . . does not create a 'negative inference' limiting the scope of the Act to the specific problem that motivated its enactment." *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 679 (1983). See also *United States v. Turkette*, 452 U.S. 576, 591 (1981). Similarly here, the mere fact that generic drug manufacturers were the catalyst for passage of section 271(e)(1) does not indicate that they were its only beneficiary.

The flaw in Lilly's interpretation of the legislative history of section 271(e)(1) can be highlighted by reference to the legislative history of section 156. Despite the fact that section 156 expressly encompasses devices,³⁰ its entire legislative history suggests that it is solely concerned with drugs. See App. A. There is no mention of the problems or benefits that section 156 provides medical device manufacturers. Even in the history of the 1988 amendments, committees of Congress continued to refer consistently to section 156 as a bill to benefit the drug industry even though devices are expressly covered. See App. B. If Lilly's citations at Pet. Br. 23-24 prove that devices were excluded from section 271(e)(1), the same reasoning would compel the Court to draw the manifestly incorrect conclusion that Congress did not provide patent term extension for devices in section 156.

Congressional focus on drugs in discussing sections 156 and 271(e)(1), even while *legislating* more broadly, was understandable. Section 271(e)(1) was intended to overrule the Federal Circuit's decision in *Roche*, 733 F.2d 858. The *Roche* case involved generic drugs, so members of Congress naturally spoke about generic drugs.

It also is not difficult to understand the presence of competing drugs interests, and the absence of competing device interests, in the legislative debates. The drug industry is composed of pioneer drug manufacturers and generic drug manufacturers which had directly competing interests at stake in the DPC-PTR Act. The device industry was and is not so divided; every company strives to be an innovator. *Orphan Drug Hearings*, *supra* p. 33,

30. Reference to devices was required in Section 156 because the calculation of the *length* of extension available depends upon the nature of the "product" as a result of the differences in testing delays incurred by each. See 35 U.S.C. §§ 156(f)(1) and 156(g)(3).

at 23 (The Commissioner of the FDA said "unlike drugs, carbon copies of devices are not the rule"). See also Smith, *Device Pre-market Approval: Lessons from the Drug Approval Experience*, 38 Food Drug Cosm. L.J. 4, 11 (1983). Regulated implantable devices such as pacemakers, heart valves, and the PCD are constantly evolving products of the latest technology, and are not "generic" in the same sense as an off-patent drug. Furthermore, when the DPC-PTR Act was passed, the effects of testing delays were not yet as apparent to the device makers as they were to drug manufacturers.³¹ The absence of device manufacturers in the legislative history surrounding sections 156 and 271(e)(1) is thus not surprising, nor does it indicate that the latter section excludes medical devices.

More generally, the absence of reference to devices in the legislative history of section 271(e)(1) is unpersuasive because it simply "is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history" *Pittston Coal Group v. Sebben*, 109 S. Ct. 414, 420-21 (1988). This Court repeatedly has interpreted statutes in accordance with their terms, even when to do so would have effects not mentioned in the legislative history. See, e.g., *Mansell v. Mansell*, 109 S. Ct. 2023, 2030 (1989); *Ron Pair*, 109

31. Although device regulating power was granted to the FDA in 1976, broad scale implementation did not occur for years. Adler, *supra* note 1, at 520; Kahan, *supra* note 29, at 292; Benson, *A Look at the Progress of the Food and Drug Administration's Medical Device Program*, 40 Food Drug Cosm. L.J. 95, 99-100 (1985) (Dep. Dir. of the Center for Devices and Radiological Health). It had taken seventeen years for the drug industry to move Congress for relief from lengthy FDA testing requirements. The statutory change requiring drug makers to undertake testing to obtain FDA approval occurred in 1962, but the first patent term extension bill was introduced in 1979. H.R. 3589, 96th Cong., 1st Sess. (1979).

S. Ct. at 1031 & n.6; *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499-500 (1985); *Newport News*, 462 U.S. at 679. "This Court frequently has observed that a statute is not to be confined to the 'particular application[s] . . . contemplated by the legislators.' This is especially true in the field of patent law." *Diamond*, 447 U.S. at 315-16 (citations omitted). Congressional focus on drugs rather than devices does not mean that statutory text with a broader reach can be disregarded.³²

Legislative history may have a role to play in clarifying ambiguities on the face of a statute. It is not, however, proper to use legislative history in an effort to *create* ambiguity where none exists. *Pierce v. Underwood*, 108 S. Ct. 2541, 2550-51 (1988); *Burlington N. R.R. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987); *James*, 478 U.S. at 604-05. Section 271(e)(1) plainly makes it not an act of patent infringement to make, use or sell *any* "patented invention" (with exceptions that do not apply here) for submissions "under a Federal law which regulates . . . drugs." Any language in the legislative history which implies that the statute does not reach some patented inventions used for the submission of information under such a law (*see supra* note 26) is in conflict with the plain terms of the statute and is entitled to no weight. *Davis v. Michigan Dep't of Treasury*, 109 S. Ct. 1500, 1504 n.3 (1989) ("Legislative history is irrelevant to the interpretation of an unambiguous statute.").

32. Alternatively, section 271(e)(1) could be viewed in its role as remedial legislation to solve the conflicts between the FDA approval process and the patent system. As such the section should be "literally construed to suppress the evil and advance the remedy." *Sutherland*, *supra* note 6, at § 60.01. Thus, even if Congress corrected the regulatory patent problem believing it did so only for drugs, when similar problems became apparent with respect to medical devices, the same remedy should be applied by the courts to the device problem.

To disprove the plain meaning of section 271(e)(1), Lilly must make an affirmative showing of an intent to exclude devices from the scope of section 271(e)(1). Statutory language that is unambiguous "must ordinarily be regarded as conclusive" in the absence of "a clearly expressed legislative intent to the contrary." *Turkette*, 452 U.S. at 580. Without a clear indication that Congress focused directly on this issue, "there is no basis for reading into its actions an intent to modify the plain meaning of the words" in the law as enacted. *Diamond*, 447 U.S. at 314. At most Lilly has shown that Congress intended to *include* drugs; it has not shown an intent to *exclude* devices.

C. Congress Decided That The Public Interest In Free Competition Is More Important Than A Patentee's Interest In Indirect Patent Term Extension

Section 271(e)(1) is a statutory recognition of two well-accepted principles: that the public interest supersedes the patentee's right to profit, and that the patent system is a strictly circumscribed exception to free competition. Enforcement of those principles is at least as important in the case of devices as drugs.³³ Exempting device testing opens new therapies and encourages innovation in rapidly evolving technologies.

The patentee's right to exclusivity is not all-encompassing. As this Court noted in *Kendall v. Winsor*, 62

33. Lilly argues that permitting device testing would represent an unconstitutional "taking" from device patentees. Pet. Br. 31-32. But that argument is grounded on the false premise that the permitted drug testing under section 271(e)(1) is restricted to bio-equivalency testing. *See* Sec. II. D, *supra*. Moreover, Congress had reasons that apply equally to drugs and devices that section 271(e)(1) did not represent a "taking." H.R. Rep. 98-857(II), *supra* p. 27, at 27-30.

U.S. (21 How.) 322, 328 (1859), "that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."

Thus, this Court has defined the patentee's right as "a right to be free from competition in the practice of the invention." *Mercoide*, 320 U.S. at 665; see also W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890). Such freedom from competition is generally disfavored in the law and is granted only to the extent necessary to secure countervailing benefits. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 530-31 (1980). There is a "congressional understanding" that "free exploitation of ideas will be the rule." *Bonito Boats*, 109 S. Ct. at 978; see also *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964) ("the patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition."); *Sony Corp. of America v. Universal City Studios*, 464 U.S. 417, 429 (1984) (The monopoly privileges of patent and copyright are "intended to motivate the creative activity of authors and inventors . . . and to allow public access to the products of their genius after the limited period of exclusive control has expired."). Section 271(e)(1) evinces a Congressional choice to apply that policy to products requiring FDA testing.³⁴

34. The preference for immediate competition long has been an integral element of the patent system. In *Pennock v. Dialogue*, 27 U.S. (1 Pet.) 1, 19 (1829) this Court stated:

[T]he main object [of the patent system] was 'to promote the progress of science and useful arts;' and this could be done best by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having a due regard to the rights of the inventor.

(Emphasis added).

A conclusion that it covers medical devices supports that Congressional goal.

Lilly is asking that its patent monopoly be effective to preclude FDA testing until the end of its extended patent term. That is similar to the respondent's request in *Deepsouth*, 406 U.S. at 518, and should be answered in the same way. This Court should "consider petitioner's claim in light of this Nation's historical antipathy to monopoly and of repeated congressional efforts to preserve and foster competition," and should "require a clear and certain signal from Congress before approving the position of a litigant who . . . argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought." *Id.* at 530-31.

D. Congress Would Not Have Made Section 271 (e)(1) Depend Upon The Difficult And Indefinite Distinction Between Drugs And Devices

Medtronic's contention that Congress did not differentiate between "drugs" and "devices" in section 271(e)(1) is supported by the fact that a bright line between the two does not exist. In a similar situation, this Court noted that its "conclusion that neither the language of the Rule nor the intent of its framers call[ed] for a distinction between 'fact' and 'opinion' is strengthened by the analytical difficulty of drawing such a line." *Beech Aircraft Corp. v. Rainey*, 109 S. Ct. 439, 449 (1988).

Any attempted exclusion of devices from section 271 (e)(1) ignores the fact that "the industry, the courts and others—including [the FDA]—have found it difficult to draw a distinction between drugs and devices, and to know how narrowly or broadly to define devices."

Benson, *supra* note 31, at 99-100; Kahan, *supra* note 29, at 59 (drug/device distinction is one of the most "convoluted issues now facing the FDA").³⁵

Definitional difficulty has arisen when a product combines features of both drugs and devices, and in drug delivery systems.³⁶ For instance, an atomizer or syringe is regulated as a device,³⁷ but if sold pre-filled with a drug, the entire system is regulated as a drug. Thus, according to Lilly, one could not do FDA testing during the patent term of an improved patented syringe, *unless* it was tested pre-filled with a drug. Congress cannot have meant the section 271(e)(1) testing exemption to depend on this meaningless difference.

35. The FDA Action Plan for 1990 states that resolving definitional problems between "drugs" and "devices" is an agency goal, and the FDA has formed a task force to address the problem. Kahan, *supra* note 29, at 62. See also Dept. of Health & Human Services, FDA, *A Plan For Action Phase III* (1989). Currently, both the Drug Center and the Device Center within the FDA have been required to create an office to resolve disputes over whether products are drugs or devices. Kahan, *FDA Regulation of Combination Drug and Device Products*, Clinica No. 327 at 13 (Nov. 23, 1988).

36. Products combining features of both drugs and devices include a bone cement with an antibiotic and a toothpaste with fluoride. The first was deemed a device, the second a drug. Similarly, the FDA found a condom with a spermicide is a device, but that a paper tissue impregnated with a germicidal agent is a drug. Dormer, *Drug/Device Distinctions . . . What Has Really Happened*, 41 Food Drug Cosm. L.J. 201, 205 (1986) [hereinafter Dormer]. Another difficulty is classifying products that "seem" more like drugs than devices. Barium sulfate, an injectable dye used as a contrast medium to enhance cancer-detecting x-rays, is regulated as a drug even though it does not operate by chemical or metabolic action. Difficulty exists with combination products where the device function is different than the drug (catheters tipped with antibiotic, pacemaker leads which elute steroids). In some cases, even use of human tissue is regulated as a device, although it plainly satisfies the definition of a biological product. Kahan, *supra* note 29, at 62. Implantable drug infusion pumps and skin patches which release drugs also create definitional problems. Kahan, Clinica No. 327 *supra* note 35, at 14.

37. Dormer, *supra* note 36, at 204 n.11.

For infringement to depend upon a drug/device distinction implicitly assumes that some authoritative entity will draw that line. But, it is unlikely that Congress would have given the FDA authority to make a classification decision that would determine the wholly unrelated question of patent infringement. The FDA's mission is to promote public health. It is guided by a statutory definition in classifying products as drugs or devices, (21 U.S.C. § 321 (g)(1) & (h) (1982)) but in gray areas the agency makes the classification by balancing safety and efficacy with the need to give the public speedy access to medicinal improvements.³⁸ Kahan, *supra* note 29, at 58. Definitions made in terms of those criteria do not form a rational basis for deciding infringement questions.³⁹ Furthermore, the FDA's decision-making process should not be skewed by adding unrelated patent consequences to the definitional equation.⁴⁰

38. Furthermore, "the FDA has been known to be inconsistent in determining regulatory jurisdiction over products that arguably could be considered either drugs or devices." Kahan, *supra* note 29, at 59. The FDA also has reclassified products from drugs to devices. *Id.* at 62; 54 Fed. Reg. 27741.

39. The FDA's classification of condoms with spermicide is illustrative. Because the spermicide (a drug) was considered supplemental to the contraceptive purpose of the product, the FDA considered it a "device" and regulated it as such. However, when it was discovered that the spermicidal drug was also a viricide that killed the AIDS virus, the manufacturers wanted to advertise that effect. The FDA ruled that to do so would give the viricide effect prominence and would require reapproval of the entire product as a "drug." Kahan, *supra* note 29, at 61. Congress cannot have meant the availability of the infringement exemption to depend upon the purpose for which a product was advertised.

40. One commentator has publicly advised companies to take section 271(e)(1) considerations into account in deciding whether to lobby the FDA for a drug or device classification. *Id.*; Dormer, *supra* note 36, at 206.

Congress has long been aware of these definitional difficulties⁴¹ and would not have made a patent infringement exemption depend on a distinction that often cannot be drawn.

IV. FDA-MANDATED TESTING OF DEVICES SHOULD NOT BE HELD TO BE PATENT INFRINGEMENT EVEN IF SECTION 271(e)(1) IS DEEMED INAPPLICABLE

The basis for the district court's holding that FDA-mandated experimental testing of a product can constitute patent infringement is the Federal Circuit's controversial decision in *Roche*. That decision relegated the long recognized concept of excusable experimental use to a "dilettante affair" since little if any modern experimentation is undertaken without any ultimate commercial purpose which *Roche* made the touchstone of infringing "use" under section 271(a). *Roche*, 733 F.2d at 863. *Roche* also had the effect of installing the "regulatory" patent as a firm reality for products subject to lengthy FDA testing. The swift reversal of the *Roche* decision by Congressional enactment of section 271(e)(1) was seen by the Federal Circuit as a "repeal by implication" of its conclusion that infringing "use" under section 271(a) included FDA testing. Pet. App. 6a (citing *United States v. Fausto*, 108 S. Ct. 668, 676 (1988)).

41. See Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce, 98th Cong., 1st Sess., Oversight Report on FDA Implementation of the Medical Device Amendments of 1976 (Comm. Print 98-F) (1983). See also Boguslanski, *Classification and Performance Standards under the 1976 Medical Device Amendments*, 40 Food Drug Cosm. L.J. 421, 422 (1985); Schwartz, *Performance Standards under the Medical Device Amendments: A Flawed Process in Need of Reform*, 39 Food Drug Cosm. L.J. 318 (1984); Dept. of Health & Human Services, FDA, *Working Relationships: Agreement Among the Bureaus of Medical Devices (BMD), Radiological Health (BRH), Biologics (BoB)* (1982); 44 Fed. Reg. 24236 (April 24, 1979).

If this Court were to decide that Congress overturned the *Roche* decision only with respect to drugs when it enacted section 271(e)(1), it still would be appropriate to inquire whether FDA-mandated testing of devices constitutes patent infringement in the first place.⁴² The *de facto* extension of patent term created by the "regulatory patent" in the health field by FDA regulatory delay for devices such as the PCD, and the consequent anti-competitive and health inhibiting results, should not be countenanced. Absent a preclusive statute, this Court should hold, as a matter of precedent and patent policy, that pre-expiration testing of medical devices mandated by the FDA is not an infringement under the Patent Act.

Congress cannot grant patents for other than a limited time or in a way that does not promote progress in science.⁴³ Thus a patent grant cannot be perpetual or indefinite. Congress was well aware of that limitation when it stated the precise purpose of section 271(e)(1): "prevention of [FDA experimental] activity would extend the patent owner's commercial exclusivity beyond the patent expiration date." H.R. Rep. 98-857(1), *supra* p.7, at 45-46.

The regulatory barrier to free competition created by FDA testing delays after expiration of a patent contravenes the "congressional understanding" that "free exploitation of ideas will be the rule." *Bonito Boats*, 109 S. Ct. at 978; *Dubilier*, 289 U.S. at 186-187 (after

42. If *Roche* was a "narrow" holding as Lilly asserts (Pet. Br. 25), then the issue of whether FDA testing of medical devices is a "use" under section 271(a) has never been decided.

43. The Constitution empowers Congress "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const., art. I, § 8, cl. 8.

patent's expiration, public should have right to use invention "without restriction"); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896) ("[O]n the expiration of a patent the monopoly created by it ceases to exist.").

The mandate of *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945), can be effectuated only if the Court reads the FD&C Act to have effectively created a testing exemption to the definition of "use" in 35 U.S.C. § 271(a).

The nature and extent of the legal consequences of the expiration of a patent are federal questions, the answers to which are to be derived from the patent laws and the policies which they adopt. By the patent laws Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time, . . . and that upon the expiration of the patent the public be left free to use the invention.

* * *

The public has invested in [free use of the patent's disclosure] by the grant of a monopoly to the patentee for a limited time. Hence any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws.

Id. at 255-56. See also *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 118 (1938); *Brulotte v. Thys Co.*, 379 U.S. 29, 31 (1964); *Boggild v. Kenner Products*, 776 F.2d 1315, 1318 (6th Cir. 1985), cert. denied, 477 U.S. 908 (1986) ("Hence, efforts to extend or

reserve the patent monopoly beyond the seventeen years contravene the policy and purpose of the patent laws.").

To the extent that the existence of FDA regulatory testing requirements confers market exclusivity on a patentee after the patent expires, it is in derogation of Congress' implementation of the Constitutional mandate in Article I, section 8, clause 8, and this Court's consistent practice of striking down any "attempted reservation or continuation" of the patent monopoly. *Scott Paper*, 326 U.S. at 256. Nothing in the FD&C Act was meant to perpetuate an effective monopoly as the Sixth Circuit recognized in *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480 (6th Cir. 1982):

The Federal Food, Drug, and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application.

Id. at 484. Perpetuating a "regulatory patent" violates the warning sounded by this Court in *Sears* that "the patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition." 376 U.S. at 230-31 (footnote omitted).

Contrary to the holding in *Roche*, the FDA testing performed by Medtronic in satisfaction of a Federal statutory requirement should be treated as a non-infringing experimental "use" analogous to the "fair use" permitted in the case of copyrights.

Even copying for noncommercial purposes may impair the copyright holder's ability to obtain the rewards that Congress intended him to have. But a

use that has no demonstrable effect upon the potential market for, or the value of, the copyrighted work need not be prohibited in order to protect the author's incentive to create. The prohibition of such non-commercial uses would merely inhibit access to ideas without any countervailing benefit.

Sony, 464 U.S. at 450-51.

Lilly is not the first patent holder that has attempted to use laws other than the patent statute to extend its monopoly position beyond patent expiration. In *Kellogg*, 305 U.S. 111, the patentee claimed that the design and appearance of the product (shredded wheat) had acquired "secondary meaning" and therefore was entitled to post-patent protection under the trademark laws. The Court held that the policy and purpose of the patent laws require that patented designs become public property after the seventeen year patent term, even if the designs have come to identify the product with a single source in the minds of the public. The Court unequivocally rejected the concept of *de facto* patent monopoly extension based on the trademark laws. See also *Lucien Lelong, Inc. v. Lander Co.*, 164 F.2d 395, 397-98 (2d Cir. 1947). More recently, in *Bonito Boats*, 109 S. Ct. at 971, this Court prevented the use of state law to create patent-like protection at odds with the policies of the Patent Act. This Court also should reject Lilly's attempt to use FDA regulation as a way of extending its patent in contravention of the Constitutional mandate and the unvarying policy of this Court to ensure that patents last only for a limited and definite time.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

JOHN F. LYNCH
Counsel of Record
W. BRYAN FARNEY
W. DAVID WESTERGARD
ALBERT B. DEEVER
ARNOLD, WHITE & DURKLE
P.O. Box 4433
Houston, Texas 77210
Counsel for Respondent

Dated: - January 5, 1990

APPENDIX A

Selected Passages From The Legislative History of Section 201 (35 U.S.C. § 156) of Title II of the Drug Price Competition-Patent Term Restoration Act of 1984 (Emphasis added)

Remarks of Rep. Derrick, 130 Cong. Rec. H8703 (daily ed. Aug. 8, 1984):

It is hoped that this extension of exclusive rights will encourage increased research and development efforts by *pharmaceutical companies*.

* * *

It also helps to restore the incentive of patent protection to those *drug manufacturers* that spend millions upon millions of dollars in the search for new drugs.

Remarks of Rep. Waxman, 130 Cong. Rec. H8706 (daily ed. Aug. 8, 1984):

Research-intensive firms predict that declining patent term will result in the development of fewer innovative products.

Remarks of Rep. Kastenmeier, 130 Cong. Rec. H8708 (daily ed. Aug. 8, 1984):

In response to the problems of the *research-based pharmaceutical houses*, legislation was offered to restore patent life lost through regulatory review.

* * *

The OTA (Office of Technology Assessment) study, "Patent Term Extension and the Pharmaceutical In-

2a

dustry," found that since 1966 the average effective *patent terms of drugs* had declined.

* * *

[T]he FDA has erected a set of substantial barriers to the market entry of *generic substitutes*.

* * *

The failure of patent term legislation last Congress was primarily the result of our failure to view the regulatory and patent problems of the *drug industry* as a whole, as recommended by OTA.

Remarks of Rep. Hyde, 130 Cong. Rec. H8709-10 (daily ed. Aug. 8, 1984):

However, for certain products such as *chemicals and medications*, the 17-year patent term has been unintentionally eroded by Federal premarket testing and regulations.

* * *

Shorter patent life translates into falling rates of return, which translates into falling investment in research and development, which translates into fewer and fewer new *medicines* coming on the market.

* * *

This reduction in the number of *drug innovations* strongly indicates that the public is being deprived of new therapies. The decline in *pharmaceutical patent lives*, the result of inadvertence rather than congressional intent, will erode the investment research incentive provided by the traditional 17-year patent term.

Remarks of Rep. Rodino, 130 Cong. Rec. H8713 (daily ed. Aug. 8, 1984):

3a

The *pharmaceutical industry* in the United States has long been an important element of our economic physical well-being.

* * *

The *pharmaceutical industry* will benefit substantially under this bill.

* * *

Although Congress never intended it, the time consumed in meeting these FDA requirements is, in effect, subtracted from the *patent lives of drugs*.

* * *

Under the bill H.R. 3605, for every *drug* they test and have reviewed at the Food and Drug Administration [FDA], a generally corresponding patent term extension will be available. The availability of such a patent term extension has long been an important legislative goal for *the industry*. It is my hope that with enactment of this bill we will see a blossoming of new research and development activities. Once patent term restoration becomes law there will be an added incentive to pursue research for new drug products.

Remarks of Rep. Minish, 130 Cong. Rec. H9143 (daily ed. Aug. 8, 1984):

Extension was included to help protect the investment in research and development that manufacturers undertake to develop *pioneer drugs*.

APPENDIX B

Selected Passages From The Legislative History of Section 201 (35 U.S.C. §§ 156 & 271(e)) of the Generic Animal Drug and Patent Term Restoration Act (Emphasis added)

Report of Senate Committee on Labor and Human Resources on S.2407, S. Rep. No. 448, 99th Cong. 2d Sess. at 2, 13 (1986):

This bill is modeled after the Drug Price Competition and Patent Term Restoration Act of 1984 ("DPC/PTR"), Pub. Law 98-417. Its purpose is to extend to veterinary drugs and biologicals the generic competition and restored patent life *afforded human pharmaceuticals by the DPC/PTR Act*.

* * *

The bill adopts entirely the patent term restoration formula and process that Congress concluded was *appropriate for human pharmaceuticals and biologics in 1984*.

* * *

Section 202 [35 U.S.C. § 156]: This section adds veterinary drugs and biologics into the patent term restoration formula that *already exists for human drugs and for food additives*, including those intended for use in animal feed.

* * *

Section 203 [35 U.S.C. § 271(e)]: This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to *human pharmaceuticals*.

House Report on H.R. 4892, H.R. Rep. No. 972, 100th Cong., 2d Sess., pt. 1, at 2, 3, pt. 2 at 15 (1988):

The purpose of the bill is to create in the animal drug industry similar conditions for generic drugs and patent term restoration *as Congress did in the human drug industry in 1984* with the "Drug Price Competition and Patent Term Restoration Act" (Public Law 98-417).

* * *

H.R. 4982 thus would extend to animal drug products *those benefits already established for human drugs* through the "Drug Price Competition and Patent Term Restoration Act" of 1984.

Remarks of Rep. Kastenmeier on H.R. 4892, 134 Cong. Rec. H9786 (daily ed. Oct. 6, 1988):

In 1984 — after 5 years of legislative effort — the Congress enacted a set of rules to govern the granting of patent term extension *for human drugs*.

Opening statement of Sen. Hatch, *Animal Drug Amendments and Patent Term Restoration Act of 1986: Hearing on S. 2407 Before the Senate Comm. on Labor and Human Resources*, 99th Cong., 2d Sess. 1 (1986):

[T]he Drug Price Competition and Patent Term Restoration Act . . . had two simple goals. First, to encourage competition *in the pharmaceutical industry* by dramatically expanding the Food and Drug Administration's ability to approve generic drugs. And second, to provide an incentive *for the research-based pharmaceutical companies* to continue their trail-blazing efforts at research and development by restoring marketing time lost during the expensive and time-consuming FDA approval process.

In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY,

v.

Petitioner,

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY BRIEF
ON THE MERITS

TIMOTHY J. MALLOY

Counsel of Record

GREGORY J. VOGLER

LAWRENCE M. JARVIS

MCANDREWS, HELD & MALLOY, LTD.

Northwestern Atrium Center

500 West Madison Street

Chicago, Illinois 60606

(312) 707-8889

Of Counsel:

LEROY WHITAKER

JOHN C. JENKINS

MARY THERESE CROUSE

ELI LILLY AND COMPANY

Lilly Corporate Center

Indianapolis, Indiana 46285

EDWARD P. GRAY

CARDIAC PACEMAKERS, INC.

4100 Hamline Avenue North

St. Paul, Minnesota 55112

Counsel for Petitioner

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**In The
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ELI LILLY AND COMPANY,

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v.

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**PETITIONER'S REPLY BRIEF
ON THE MERITS**

SUMMARY OF THE ARGUMENT

It defies basic tenets of statutory construction and common sense to suggest, as respondent Medtronic, Inc. ("Medtronic") does with its contortions of logic, that the restrictive statutory language "development and submission of information under a Federal law which regulates . . . drugs" means the development and submission of information for any product under the more expansive Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Congress would not, and did not, use a narrow term—"drugs," which expressly excludes devices under the FD&C Act—to include devices and all other products covered by the much broader FD&C Act.

The "plain language" argument of Medtronic and some of its supporting *amici* contradicts the Court of Appeals' opinion below. Medtronic does not attempt to support the

reasoning of the Court of Appeals' opinion. The Court of Appeals, Medtronic, and its supporting *amici* also disagree over Medtronic's argument that there is clear support in the legislative history for inclusion of "medical devices" in Section 271(e)(1). The positional chaos among Medtronic and its supporting *amici* results from the inescapable language of the statute in question limiting its application solely to drugs.

Neither Medtronic nor its supporting *amici* can point to a single reference in the legislative history of Section 271(e)(1) suggesting the possibility of exempting medical devices from patent infringement. There are none. Instead, Medtronic reconstructs the legislative commentary of Sections 271(e)(1) and 156 to distort Section 271(e)(1). The House Committee reports clearly distinguish between the scope of Section 271(e)(1) (drugs) and Section 156 (drugs, medical devices, food additives, and color additives) in both the language of the statute *and* the textual discussion. H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 15, 17, 20 (1984).

In apparent recognition of the infirmity of its statutory arguments, Medtronic improperly raises for the first time in this litigation a new issue—a judicially-created "experimental use" exception to patent infringement. Even if the argument were considered, however, this alleged common law infringement exemption has no merit. As Medtronic's supporting *amicus* Dr. Denton Cooley admitted, "the present law . . . does not exempt from infringement experimental use where there is an ultimate commercial motive, however remote." Cooley Br., pp. 3-4.

Under the guise of testing for regulatory approval, Medtronic and its supporting *amici* desire the right to copy and infringe any patent for medical devices, food additives, color additives, and all other FDA-regulated, non-drug

products throughout the entire patent term.¹ Medtronic's policy arguments (strongly countered by Lilly and its supporting *amici*) are appropriate for Congress, not this Court, to consider. "Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *United States v. Rutherford*, 442 U.S. 544, 555 (1979).

ARGUMENT

I. The Plain Language of the Statute Expressly Limits Section 271(e)(1) to Development and Submission of Regulatory Information Necessary for Drug Approval

Instead of reading Section 271(e)(1) as a whole and giving meaning to all of its words, Medtronic improperly combines isolated interpretations of selected phrases to artificially support its position. Medtronic first interprets the phrase "patented invention," and, overlooking the language "solely for uses reasonably related to the development and submission of information under," construes the phrase "Federal law which regulates . . . drugs" to mean the *entire* FD&C Act. Medtronic then makes a tortuous leap in logic to conclude that since Medtronic's medical devices may be described as a "patented invention" and since its testing is done under the FD&C Act, the criteria of Section 271(e)(1) are met. Medtronic Br. p. 6. Medtronic's piecemeal interpretation of Section 271(e)(1) is compelling

¹ It is ironic that Medtronic, which once owned the patent rights in suit in the early 1970's but abandoned an implantable defibrillator project for, *inter alia*, marketing reasons (Pet. App. 24a; Tr. Ex. 173; Trans. Day 2; 30-32), claims to be the protector of the public interest. Medtronic and some of its supporting *amici* stood on the sidelines for a decade or more letting Dr. Mirowski, Lilly, and Lilly's predecessors-in-interest assume the entire financial risk to obtain therapy acceptance for the pioneer lifesaving implantable defibrillator. Once therapy acceptance was achieved, these competitors then decided to launch their infringing imitative implantable defibrillators.

evidence of its strained, improper statutory construction.²

The restrictive language "development and submission of information under a Federal law which . . . regulates drugs" means what it says. It grants a narrow exemption from patent infringement for development and submission of regulatory information necessary for *drug* approval.³ Although referring to the drug provisions of more than one Act of Congress, the statute does not encompass the entire FD&C Act. It is restricted to regulatory submissions under a "Federal law regulating . . . drugs," not any submissions under the FD&C Act, a term used only a few lines earlier in the same subsection. Medtronic's statement that the phrase "under a Federal law regulating . . . drugs" refers to provisions in more than one Act of Congress is meaningless. The language still is limited to the *drug* submission provisions of those acts.

Medtronic's infringing devices never can be used "for development and submission of information *under* a Federal law which regulates . . . drugs." (emphasis added). Information for premarket approval requirements of (human) drugs is developed and submitted under drug provisions such as 21 U.S.C. § 355 (human pharmaceuticals).⁴ In contrast, Medtronic's infringing devices are used

² Under Medtronic's interpretation, the same outcome — bringing medical device testing within Section 271(e)(1) — would result had the last phrase of the statute read "Federal law regulating . . . color additives," or for that matter, "foods" or "cosmetics." The plain language does not support an interpretation that any product is covered by Section 271(e)(1) merely because it happens to be regulated in an Act of Congress that *also* regulates drugs.

³ Medtronic is wrong in its argument that Lilly narrows the definition of the term "patented invention" to mean "drug-related invention." Medtronic Br. p. 10. Lilly interprets Section 271(e)(1) only as required by its operative language and correct tenets of statutory construction. Medtronic's reliance on the rules of grammar and syntax is misplaced.

⁴ Contrary to Medtronic's allegations, Lilly does not maintain that a "Federal law which regulates . . . drugs" refers *only* to 21 U.S.C. § 355. However, if animal drugs and veterinary biological products are excluded, as in the original enactment of Section 271(e)(1), Section 355 constitutes the predominant law *under* which information for premarket approval of drugs is developed and submitted.

for development and submission under a Federal law which regulates devices, i.e., 21 U.S.C. §§ 360e and 360j. Data submission requirements for food additive petitions and color additive petitions are described in 21 U.S.C. §§ 348 and 376, respectively. It would be odd, to say the least, for Congress to identify the data submission and approval requirements for medical devices, food additives, and color additives as being under a "Federal law which regulates . . . drugs."

It is true that drugs, devices, and other products may be regulated under the same Act, such as the FD&C Act.⁵ However, as Medtronic admits (Medtronic Br. p. 20), devices are not regulated, nor is information developed or submitted for governmental approval, *under* any drug provision or under the designation "drugs." Drugs and medical devices are distinct and separate products.⁶ The FD&C Act

⁵ Medtronic relies upon 21 U.S.C. § 331 as regulating both drugs and devices. This argument is irrelevant, and merely advances a more narrow version of its erroneous conclusions drawn from the FD&C Act being a law that regulates drugs and devices as well as other products. No information is developed or submitted under 21 U.S.C. § 331. Moreover, *Section 331 treats drugs and devices distinctly*. Although it may prohibit certain acts relating to drugs, devices, foods, and cosmetics, Section 331 offers no support that medical devices are a subset of drugs or are included in the meaning of the term "drugs," or that Congress mistakenly thought so. The language of 21 U.S.C. § 331 actually negates Medtronic's arguments. It is further proof that whenever Congress enacts statutes covering medical devices and drugs, it speaks clearly and identifies *each* by name. In contrast, Section 271(e)(1) only identifies drugs.

⁶ Medtronic alleges that "a bright line between [drugs and devices] does not exist." Medtronic Br. p. 41. This is another of Medtronic's irrelevant arguments highlighting the desperation of its Section 271(e)(1) interpretation. In rare cases, there may be a dispute about whether a product is a drug, medical device, or both. Many ramifications result from the selected classification, including, *inter alia*, the governing provisions of the FD&C Act. Before any testing begins, however, the FDA determines the classification of the product with an opportunity for court review from dissatisfied requesters. Once the classification is made, there is no dispute about which regulations govern the development and submission of information to obtain FDA approval for drugs or medical devices. In fact, 35 U.S.C. § 156 requires that a distinction between drugs and devices be made, and treats patent extensions for the two differently. In any event, to the extent there is a "bright line" distinction between these two types of products, it is completely irrelevant to the statutory interpretation in question.

expressly states that the "term 'drug' . . . does not include devices or their components, parts, or accessories." 21 U.S.C. § 321(g)(1). There hardly could be a more inappropriate phrase to identify medical device uses than "uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs."

II. Medtronic Misuses Related Statutory Language and the Legislative History

A. Sections 271(e)(2) and (e)(4) Are Equally Necessary for Devices Had Section 271(e)(1) Included Medical Devices

In its main brief, Lilly explains that had Congress included medical devices in Section 271(e)(1), it also would have included medical devices in the patent holder protection provisions of Sections 271(e)(2) and (e)(4). Petitioner's Br. pp. 17-18. *Compare* proposed Senate Bill S.622 which would add medical devices to Sections 271(e)(1), (e)(2), and (e)(4) (Pet App. 60a-61a). Medtronic attempts to address this glaring omission from their version of the statute by theorizing that those special protections are unnecessary for medical devices. Medtronic then states "there are no provisions, comparable to those for drugs, for abbreviated safety and efficacy testing of medical devices *in the class of implantable defibrillators*." Medtronic Br. p. 29 (emphasis added). Medtronic's statement misses the point.⁷

⁷ While "abbreviated" applications (*i.e.*, those involving bioequivalence testing) are unavailable for medical devices, many medical devices other than implantable defibrillators do not require full premarket clinical trials prior to marketing. As Medtronic's supporting *amicus*, the American Association of Retired Persons ("AARP"), explained, the vast majority of medical devices can qualify for marketing without clinical trials if they are "substantially equivalent" to a device marketed before 1976. AARP Br. p. 12. See, 21 U.S.C. §§ 360c(a)(3), c(c)(2), and c(f)(1); 21 C.F.R. § 814.1(c)(1). Medtronic's selection of implantable defibrillators (which are not eligible for marketing under the "substantially equivalent" provisions) as "exemplary" is misleading and highlights the error of its argument.

Section 271(e)(2) provides an early mechanism for the patent holder to initiate an infringement action where an infringer seeks abbreviated regulatory approval (35 U.S.C. § 355j) and commercialization before the patent expires. Without the special protections of Sections 271(e)(2) and (e)(4), the patent holder would have to wait until the infringer operates outside the scope of Section 271(e)(1), and would suffer monetary damage as well as irreparable injuries during the inherent delays of the litigation process. As evidenced by proposed S.622, the special patent protections of Sections 271(e)(2) and (e)(4) would have been equally necessary and available for medical devices had Congress included medical devices in Section 271(e)(1).

B. The Separate Products Covered by Sections 271(e)(1) and 156 Are Clearly Identified

In its main brief, Lilly explains that the statutory language of the patent extension provisions (Section 156) refers expressly to both drugs and devices while the statutory language of Section 271(e)(1) refers only to drugs. Petitioner Br. pp. 18-21. This disparate inclusion and exclusion in different portions of the same Act reveals that Congress purposely excluded medical devices from Section 271(e)(1). See, *e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983).

Medtronic argues that these differences in statutory language are irrelevant because the "entire legislative history suggests that [Section 156] is solely concerned with drugs" and thus "would compel the Court to draw the manifestly incorrect conclusion that Congress did not provide patent term extension for devices." Medtronic Br. p. 36.

Medtronic's premise is erroneous. In its section entitled "Purpose and Summary," House Report No. 98-857 clearly recognizes that Section 271(e)(1) covers only drugs while Section 156 covers drugs, devices, and other products.

Title II of H.R. 3605 [Section 156] provides for one extension of the earliest patent on certain products subject to pre-market approval. . . . These products include: human drugs, animal drugs, *medical devices, and food and color additives*.

* * *

Finally, Title II [Section 271(e)(1)] provides that it is not an act of patent infringement for a *generic drug maker* to import or to test a *patented drug* in preparation for seeking FDA approval if marketing of the *drug* would occur after expiration of the patent.

H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1, at 15 (1984) (emphasis added). The purpose and summary of the legislative history could not be more clear as to which products are encompassed by Sections 271(e)(1) and 156, respectively.⁸

C. Medtronic Distorts the Legislative History

Medtronic and its supporting *amici* could not point to a single reference in the legislative history suggesting that medical devices are included within Section 271(e)(1). In a transparent attempt to manufacture support, Medtronic surgically reconstructs that portion of the legislative history upon which it relies. Medtronic Br. p. 24. In doing

⁸ Additional legislative commentary identifies the specific products within the separate scopes of Sections 271(e)(1) and 156. See, e.g., H.R. Rep. No. 857, *supra*, Part 1, at 17 ("the products covered by [the patent extension provisions] include pharmaceuticals, medical devices"); *id.*, Part 1, at 20 ("products affected by [patent extension] would be drugs, medical devices . . ."); *id.*, Part 1, at 44 (paragraph entitled "Medical Devices" under Section 156); *id.*, Part 2, at 24 (Section 156(f) includes medical devices); *id.*, Part 2, at 32 ("products affected by [patent extension provisions] would be drugs, medical devices . . ."). See also, the Brief for the Petitioner, which sets forth the citations to the legislative history that limit Section 271(e)(1) solely to drugs. Petitioner's Br. pp. 22-24.

so, Medtronic excises key prefatory language immediately preceding the language quoted by it, and then selectively transplants language to relocate one sentence in the place of another (likewise omitted). Medtronic Br. p. 24. Compare H.R. Rep. No. 857, Part 1, at 45-46. The language excised by Medtronic from the legislative commentary is italicized below and the relocated sentence is noted:

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.

In Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., ___ F.2d ___ (Fed. Cir., April 23, 1984), the Court of Appeals for the Federal Circuit held that the experimental use of a drug product prior to the expiration date of a patent claiming that drug product constitutes patent infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires. It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date [MED-TRONIC RELOCATED THIS SENTENCE IN PLACE OF THE OMITTED (ITALICIZED) SENTENCE IN THE NEXT PARAGRAPH].

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged. *For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product.* Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. Rep. No. 857, Part 1, at 45-46 (emphasis added).

The excised language shows that the limited experimental activity exempted by Section 271(e)(1) is *bioequivalence testing* for generic drugs.⁹ Medtronic labels the Congressional statement that Section 271(e)(1) permits only bioequivalence drug testing "an understandable lapse." Medtronic Br. p. 31, n.26. Medtronic's inability to otherwise explain this legislative commentary further undermines its flawed interpretation.

There is no basis for applying the specific legislative commentary on Section 271(e)(1) to medical devices, food additives, or color additives, the other products for which the patent extensions of Section 156 apply. Analysis of the last paragraph of H.R. Rep. No. 857 reproduced above, especially the sentence omitted by Medtronic on two

⁹ While the statute also would permit *clinical testing* of patented drugs, Congress understood, as a practical matter, that manufacturers would take advantage of the "abbreviated" procedures which require only bioequivalence testing, rather than undertaking their own time-consuming clinical tests. See H.R. Rep. No. 857, Part 2, at 8. Medtronic's argument that Section 271(e)(1) applies to clinical testing of patented drugs (other than generic bioequivalence testing) raises another empty point, with no real-world consequences.

occasions (Medtronic Br. pp. 24 and 35), reveals the action Congress took to encourage immediate competition for patented drugs. "*For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product.*" *Id.*, Part 1, at 46 (emphasis added). The Congressional action on Section 271(e)(1) does not apply to medical devices.¹⁰ Under Medtronic's interpretation, medical devices can be approved anytime during the patent term because there are no Section 271(e)(2) and (e)(4) restrictions, and no regulatory exclusivity provisions or automatic provisions to delay the effective approval date as there are with drugs under 21 U.S.C. § 355(j)(4)(B). In the absence of express language, it cannot be presumed, as Medtronic urges, that Congress would take away valuable intellectual property rights from medical device patent holders.

D. Sections 156 and 271(e)(1) Are Not Coextensive in Scope or Nature

As a secondary argument, Medtronic alleges that Sections 271(e)(1) and 156 are coextensive and thus should be construed to be equal in scope, *i.e.*, since Section 156 applies to devices as well as drugs, so should Section 271(e)(1). Medtronic Br. p. 23. Again, Medtronic's premise is without merit. Section 271(e)(1) is not congruent to or coextensive with Section 156. Section 271(e)(1) applies to all drug patents whether the patent term is extended or not, and even applies to those drug patents which cannot qualify for a term extension. In contrast, only a handful of patents in an FDA-regulated field can be extended under the restrictive eligibility provisions of Section 156(a). *Cf.*

¹⁰ Medtronic's alleged justification for Section 271(e)(1) as being a *quid pro quo* for Section 156 does not apply to food additives and color additives. When a regulation is issued to govern the use of food or color additives, a copier can market its version promptly upon the expiration of the patent without any requirement to obtain FDA approval comparable to what is required for drugs. 21 U.S.C. §§ 348 (a)(2), 376(a).

Fisons PLC v. Quigg, 872 F.2d 99 (Fed. Cir. 1989) (patent term extension denied for three drug patents); *In re Alcon Laboratories Inc.*, 13 U.S.P.Q. 2d 1115 (Pat. Comm'r 1989) (patent term extension denied for drug patent).

Section 271(e)(1) applies anytime during the entire term of affected patents. On the other hand, the patent holder does not recover the full amount of patent life lost during testing and the FDA regulatory approval process.¹¹ 35 U.S.C. §§ 156(c) and (g). Sections 271(e)(1) and 156 were never intended to be coextensive in scope.

Contrary to Medtronic's arguments, the complementary exclusion of animal drugs and veterinary biological products from Sections 271(e)(1) and 156 does not establish congruency. Animal drugs and veterinary biological products are included in the definition of the term "drug" in the FD&C Act. See 21 U.S.C. § 321(g)(1); *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288, 1289 (8th Cir. 1981), cert. denied, 456 U.S. 927 (1982) (the term "drug" encompasses animal biologics). Thus, it was necessary to exclude expressly animal drugs and veterinary biological products in the original enactment of Section 271(e)(1) when Congress decided to address them in separate legislation.

III. Public Policy and Constitutional Considerations

A. Public Policy

The policy arguments raised by Medtronic and its supporting amici are for Congressional consideration. *Rutherford*, 442 U.S. at 555. Lilly and its supporting amici have set forth the policy considerations strongly favoring Congress' exclusion of medical devices and other non-drug,

¹¹ Although Lilly's predecessors-in-interest spent over fourteen years in testing and seeking FDA approval for its implantable defibrillators from 1971 (issuance of the '757 patent) until 1985 (FDA premarket approval granted), Lilly could only obtain a two-year patent extension for the '757 patent under Section 156. Lilly has not received the benefits of a patent extension for the '536 patent. However, Lilly has lost its exclusive rights to the '536 patent under Section 271(e)(1) as construed by the Court of Appeals.

FDA-regulated products from Section 271(e)(1). Petitioner Br. pp. 28-33. They will not be repeated here. The Senate Committee report on the proposed patent extension provisions in 1981 further discusses the policies supporting patent term extension. Senate Rep. No. 97-138, 97th Cong., 1st Sess., at 8-9 (1981).¹²

After a patent expires, a patent holder generally has no right to exclude others under that patent from making, using, or selling the patented invention. Exclusion of medical devices from Section 271(e)(1) gives Lilly no additional patent rights. Cases cited by Medtronic involving expansion of patent rights are inapposite.

If there are any commercial ramifications of the DPC-PTR Act that favor Lilly, those are a function of the FDA approval process, not the Congressional legislation at issue. For example, a copier can avoid any inherent delay in the FDA approval process by obtaining FDA approval prior to patent expiration based solely upon foreign activities (assuming foreign patent rights are not infringed).¹³ 21 C.F.R. § 814.15; JA 107-8. It is the copier, not Lilly or

¹² That Committee Report stated that the patent term extension provisions, which then were without any accompanying patent infringement exemption, "will have a particularly beneficial effect on small research-oriented companies." Senate Rep. No. 97-138, *supra*, at 8. The AARP in 1981, before the *Roche v. Bolar* decision, submitted a written statement in support of the concept of patent term restoration although Section 271(e)(1) exemptions were unavailable. *Id.*, at 8. This alone contradicts most of the AARP policy arguments made in this case. At the same time, representatives of the university research community (Johns Hopkins University and Massachusetts Institute of Technology) stated that the patent extension provisions benefit universities. *Id.* This contradicts the policy arguments of the amici self-proclaimed as the "Academic Research Centers" (consisting solely of the University of Minnesota and Tulane University).

¹³ There is an inherent delay in achieving full commercial productivity for copiers of *all* patented products, not just FDA-regulated products, after the expiration of the patent. The patent laws do not allow testing or mass manufacturing and warehousing of infringing products during the patent term even if the infringer is gearing up only for commercialization after patent expiration. See *Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 16-20 (Fed. Cir. 1984) (testing solely for post-patent commercialization is an infringement).

the patent laws, that ultimately controls whether the copier can market its products immediately upon expiration of the patent.

The arguments of Medtronic and its supporting *amici* that "the sky is falling" on American research and development if Section 271(e)(1) excludes medical devices and other FDA-regulated products are unfounded. The FDA regulations governing medical devices have been in effect since 1976. Until Medtronic raised the defense of Section 271(e)(1) in 1987 (three years after its enactment and four years after this litigation commenced), Lilly was not aware of anyone expressing a concern that American research would relocate to foreign countries if an FDA-testing patent exemption were not available for devices. The track record since 1976, when FDA testing regulations for devices began and patent laws prohibited all use of infringing products, including FDA testing, prior to patent expiration, shows there has been no mass exodus of American research talent or resources.

Moreover, Medtronic's reasoning also would apply to U.S. research related to *all* U.S. patents during the term of the patent since the patent laws prohibit pre-expiration testing of an infringing product intended solely for post-patent use. *Paper Converting*, 745 F.2d at 16-20. Despite these restrictions, the patent laws exist "in the hope that [t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980). Medtronic has turned this policy favoring a strong patent system on its head and applied it to infringers. Favoring improvements by infringers at the expense of eroding the stimulus for basic lifesaving inventions conflicts with the purposes of the patent system.

The only research restricted is the making, using, and selling of patented inventions, nothing more. But for the patented inventions, there would be nothing to copy, and no basic invention to improve.

The several conflicting *amici* briefs filed by interested parties from the medical device industry show that the policy arguments are for Congressional consideration in the first instance, not judicial resolution. This Court must reject Medtronic's blatant request for judicial legislation seeking a judicial response to Congress' actions and inactions. See *Medtronic Br.* p. 38, n.32.

B. Constitutional Considerations

Despite charging more than \$17,000 per device (JA 108) and proclaiming itself "the technological leaders in the tachy arena" after its first clinical PCD implant (JA 128-29), Medtronic, without support, opines that the unconstitutional "taking" of property from device patentees is identical to that considered by Congress in the limited context of bioequivalence testing for generic drugs. *Medtronic Br.* p. 39 n.33. Medtronic simply fails to appreciate that resolution of the Constitutional issues (*i.e.*, impermissible taking under the Fifth Amendment) can be avoided, and must be avoided, only by limiting Section 271(e)(1) to testing for drugs. See *Petitioner's Br.* pp. 31-32.

IV. Medtronic Improperly Raises a New Argument for the First Time In This Appeal

Medtronic now attempts to assert a new issue—an alleged judicially-created experimental use exception to patent infringement. *Medtronic Br.* pp. 44-48. This "defense" has been waived. It was never pleaded in the Answer to the Complaint, raised in the lower courts, or argued in Medtronic's opposition to Lilly's certiorari petition. The grant of certiorari is premised exclusively upon statutory construction of Section 271(e)(1). This Court must not consider Medtronic's new argument presented for the

first time in its brief in response. See, e.g., *Youngberg v. Romeo*, 457 U.S. 307, 316 n.19 (1982) (this Court declined to consider an argument raised for the first time in respondent's brief); *FTC v. Grolier, Inc.*, 462 U.S. 19, 23 n.6 (1983).

Lilly objects to Medtronic's presentation of this new issue which is clearly outside the statutory interpretation question presented to this Court in the petition for certiorari. However, without waiver of its objection, Lilly will address the issue briefly.

Medtronic seeks an across-the-board exemption to patent infringement for all FDA testing of medical devices, and presumably for all other FDA-regulated products. Medtronic Br. p. 44. This would be a gross act of judicial legislation and infringe upon the exclusive power of Congress to legislate. Congress already has demonstrated that it is active in these very areas with the enactment of the 1984 DPC-PTR Act, the 1988 Amendments to Section 271(e)(1), and the proposed amendment in 1989. Neither patent law nor the FD&C Act supports Medtronic's newly-asserted alleged exemption.

The Court of Appeals for the Federal Circuit squarely addressed the experimental use exemption in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 862-65 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984). After reviewing the history of this defense to liability for infringement of a drug patent, the Federal Circuit declined to "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when the inquiry has definite, cognizable and not insubstantial commercial purposes," as does FDA testing to obtain premarket approval. *Id.* at 863. See also *Paper Converting*, 745 F.2d at 16-20 (it is a patent infringement to test a patented product intended solely for post-patent use in a non-regulated industry). Refusing to rewrite the patent laws and indicating that it is the role of Congress

to legislate, the Federal Circuit declined to legislate a new patent infringement exception for drug testing to obtain FDA premarket approval for products. *Bolar*, 733 F.2d at 864-65. The analysis of the *Bolar* court applies equally to medical device patents and is set forth in that reported decision.

Medtronic's newly articulated defense goes hand in hand with its attempt to further delay injunctive relief by requesting a remand to the Court of Appeals.¹⁴ This Court should deny Medtronic's request that the case be remanded to the Court of Appeals for consideration of "other bases for vacating the injunction." Medtronic Br. p. 5, n.4. Medtronic abandoned its only other alleged basis, which Lilly will address briefly.¹⁵

Although mysteriously not revealed by Medtronic to this Court, presumably because of lack of merit, Medtronic contended that the patent rights for the '757 patent, extended under 35 U.S.C. § 156(b), somehow did not apply to Medtronic's devices during the extended term (October 27, 1988 through October 26, 1990). The plain language of Section 156(b) states that the patent rights are extended for "any use approved for the product" (for product claims)

¹⁴ Medtronic's request for a remand is yet another facet of Medtronic's overall strategy in this case to delay proceedings and avoid a full injunction against its infringing activities through procedural delay. Already, over six years of the patent life have expired during this litigation (filed in 1983). Medtronic substantially delayed this litigation, *inter alia*, by instituting reexamination proceedings before the Patent Office for the patents now in suit and once owned by Medtronic. Six years of willful infringement and irreparable injury to the patent holder are enough (Pet. App. 37a).

¹⁵ Despite the potentially dispositive nature of Medtronic's Section 156(b) defense to injunctive relief under the '757 patent (which is within its extended term), Medtronic failed to seek reconsideration from the Court of Appeals after its decision remanded the case to the District Court "to decide whether the injunction should be vacated, modified, or stayed." (Pet. App. 7a). Medtronic remained silent while the District Court issued a modified injunction, directly contrary to Medtronic's Section 156(b) defense, and effective during the extended term of the '757 patent.

and "any use claimed by the patent and approved for the product" (for method claims).

In this case, the "use approved" is the treatment of ventricular tachycardia and ventricular fibrillation by electric shock with an automatic implantable defibrillator (TX-600; Pet. App. 23a). Medtronic's use of its devices indisputably is identical to this "use approved" (Pet. App. 24a-25a; JA140). In fact, Medtronic initially used a CPI implantable defibrillator (the approved product) as a backup for its 7215 PCD devices (JA44). This further establishes that Medtronic's devices are used for the "use approved" within Section 156(b). Medtronic's Section 156(b) defense has no merit, and its attempt to revive the defense must be rejected.

CONCLUSION

The decision below is clearly erroneous. Lilly respectfully requests that the judgment of the Court of Appeals be reversed and the case be remanded for further proceedings with instructions to reinstate immediately the District Court's original injunction. *See, e.g.*, 28 U.S.C. § 2106; *Morton v. A Quaker Action Group*, 402 U.S. 926 (1971) (this Court reinstated preliminary injunction); *Lawlor v. National Screen Service Corp.*, 349 U.S. 322, 330 (1955) (judgment of Court of Appeals reversed and case remanded to the District Court for further proceedings). This original injunction, which the Court of Appeals refused to stay during the appeal (Pet. App. 56a), was modified solely on the basis of the Court of Appeals' erroneous interpretation of Section 271(e)(1). Once this Court corrects the Court of Appeals' erroneous interpretation, the *status quo* and fairness require immediate reinstatement of the original injunction. The extended term of the '757 patent expires

on October 26, 1990. Lilly is being continually and irreparably harmed by the lack of a full injunction against Medtronic's infringing activities (Pet. App. 37a).

Respectfully submitted,

TIMOTHY J. MALLOY
Counsel of Record
 GREGORY J. VOGLER
 LAWRENCE M. JARVIS
 McANDREWS, HELD & MALLOY, LTD.
 Northwestern Atrium Center
 500 West Madison Street
 Chicago, Illinois 60606
 (312) 707-8889—

Counsel for Petitioner

Of Counsel:

LEROY WHITAKER
 JOHN C. JENKINS
 MARY THERESE CROUSE
 ELI LILLY AND COMPANY
 Lilly Corporate Center
 Indianapolis, Indiana 46285

EDWARD P. GRAY
 CARDIAC PACEMAKERS, INC.
 4100 Hamline Avenue North
 St. Paul, Minnesota 55112

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Supreme Court, U.S.

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IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, Inc.,

Respondent.

**BRIEF FOR AMICUS CURIAE THE
PROCTER & GAMBLE COMPANY IN SUPPORT OF
PETITIONER ELI LILLY AND COMPANY**

Ronald L. Hemingway

Counsel of Record

Richard C. Witte

Julius P. Filcik

The Procter & Gamble Company

Winton Hill Technical Center

6071 Center Hill Road

Cincinnati, Ohio 45224

(513) 634-5593

Counsel for Amicus Curiae

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**BRIEF FOR AMICUS CURIAE THE
PROCTER & GAMBLE COMPANY IN SUPPORT OF
PETITIONER ELI LILLY AND COMPANY**

The Procter & Gamble Company ("P&G") files this *amicus curiae* brief in support of Petitioner, Eli Lilly and Company ("Lilly"), to reverse the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989¹

INTEREST OF THE AMICUS CURIAE

P&G (including its subsidiaries) is a manufacturer and marketer of food, drug, and cosmetic products and medical devices which are subject to regulation by the Food and Drug Administration ("FDA").² P&G also is engaged in significant

¹ P&G has received the consent of both parties for the filing of this brief. Copies of the letters granting said consent have been filed with the clerk.

² P&G is *not* a competitor of petitioner or respondent or their subsidiaries, in the field involving the medical devices of this lawsuit.

research and development in these areas. P&G relies substantially upon the patent system for protecting its hard-earned inventions that result from its investments and research efforts.

Although the type of product at issue in this case is medical devices, the Court of Appeals' holding directly affects a much broader range of products. The Court of Appeals stated:

Accordingly, we hold that Section 271(e)(1) allows a party to make, use or sell *any type* of "patented invention" if "solely" for the restricted uses stated therein.

(Pet. App. 7a)³ (emphasis in original).

Thus, the Court of Appeals' decision erodes P&G's existing and potential future patent rights in the areas of nondrug food additives and products containing color additives, as well as medical devices. The decision has significant business impact and will reduce the incentive for P&G and similarly situated companies to invest in innovation in these important fields.

For example, safety tests typically costing millions of dollars need to be conducted by P&G to obtain FDA approval of its patented food additive products. Such tests may take from five to fifteen years or more to complete.⁴ It can take another two or three years or more to obtain FDA approval for a food additive or color additive after filing a petition for approval with the FDA.

After P&G has paved the way for competitors by obtaining FDA approval for these pioneering inventions, competitors,

³ "Pet. App. 7a" refers to page 7a of the appendix of Lilly's Petition for Certiorari. P&G will refer to petitioner's appendix on several occasions using the same citation form.

⁴ P&G has filed for FDA approval for a food additive called olestra, which is a fat substitute product which embodies inventions which are the subject of existing and pending patents. The safety testing for olestra has taken nearly fifteen years. P&G's petition has been pending for over two years.

in spite of any P&G patents, can use immediately the patented inventions in research conducted to obtain FDA approval for new uses for these inventions under the Court of Appeals' interpretation of Section 271(e)(1). This can lead to competitive advantages for P&G's competitors even though they did not undertake the substantial risk and expense in inventing and then patenting and obtaining original FDA approval for the pioneering inventions. Competitors will also be permitted to conduct testing to obtain food or color additive approval of compounds which have been patented by P&G, but for which P&G has not sought approval. In either case, P&G loses exclusive rights to the control of its patented inventions in important research areas. The economic impact is substantial since P&G is deprived of exclusivity in the development of new, potentially important uses for its patented inventions. The net effect is to lessen the incentive for P&G and other innovative companies to invent and invest in pioneering products.

P&G, accordingly, has a strong interest in having this Court correct the erroneous Court of Appeals' decision and restore the full scope of patent protection for food and color additive products (as well as medical devices).

Since the controversy in this case relates to medical devices, it is expected that arguments of the Parties will focus on a comparison between drugs and medical devices, their respective regulatory approval procedures, and how such comparison relates to the intent of Congress in enacting 35 U.S.C. § 271(e)(1). Regulatory procedures for food additives and color additives are different from either drugs or medical devices. Therefore, it is believed that P&G's arguments relating to food additives and color additives will provide added assistance to the Court in understanding why Congress provided a patent infringement exemption for regulatory testing of drugs only, when it enacted 35 U.S.C. § 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984.

SUMMARY OF ARGUMENT

It is clear from the language of 35 U.S.C. § 271(e)(1) and its legislative history that the immunity from infringement which the statute provides for activities conducted to obtain approval to market FDA-regulated products is applicable only to drugs.

The only type of regulated product mentioned in the statute is drugs (and veterinary biological products added by subsequent amendment).

Congress' objective in enacting Title I of The Drug Price Competition and Patent Term Restoration Act of 1984 was to provide for the prompt marketing of generic copies of patented drugs upon expiration of the patents. In order to accomplish this, Congress provided in Title I, an abbreviated procedure for regulatory testing of generic copies of approved drugs, and since regulatory testing of patented drugs during the life of a patent had previously been held to be patent infringement, Congress also enacted Section 271(e)(1) as part of Title I in order to exempt such testing of drugs from patent infringement.

Congress did not modify the procedures for regulatory approval of medical devices, food additives and color additives, nor did it address any patent infringement issues relating to said procedures. These products present regulatory considerations which are different from drugs.

With respect to food additives, the party seeking initial approval files a petition with the FDA proposing the issuance of a regulation prescribing the conditions under which the additive is to be used. The petition is supported with appropriate test data, chemical data, etc. to establish safety and technical effect. When a regulation is subsequently issued which governs the use of the food additive, any party may market its own copy of the approved additive product in conformance with the regulation, i.e., the copier of the approved food additive may market its copy without any requirement to obtain prior approval. The situation is similar for color ad-

ditives. If the food or color additive is the subject of a patent, the copier can begin marketing as soon as the patent expires. Thus, in the case of food and color additives, and contrary to the case with drugs, there is no need for generic copiers to conduct regulatory testing during the life of a patent in order to market a generic copy of an approved additive in accordance with the regulation governing its approval. It is readily apparent, therefore, that the objective which caused Congress to enact Section 271(e)(1), i.e., to provide a means by which copies of approved, patented drugs would become available promptly upon expiration of the patent, is in no way applicable to food or color additives. This situation already existed with respect to these products prior to the enactment of Section 271(e)(1).

Under the Court of Appeals holding, the generic copier, in addition to continuing to have the benefit of a completely "free ride" on the regulatory approval obtained by the patentee of a food or color additive product, will now also be permitted to conduct regulatory testing of the patented, previously approved additive product to seek issuance of new or modified regulations to govern new or expanded uses of it. Also, non-patentees will be permitted to conduct testing to obtain food or color additive approval of patented compounds which have not previously been approved, which could then be sold in competition with other products of the patentee as soon as the relevant patents expire. Both types of testing during the term of a patent are abridgements of the exclusive rights of patentees to control the conduct of commercially motivated research on their patented inventions. An intent to abridge such valuable rights of patentees should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case.

ARGUMENT

A. It Is Clear From the Language of the Statute and Legislative History That Congress Intended Section 271(e)(1) to Apply Only to Drugs

The Court of Appeals in this case determined that infringing medical devices, and other nondrug, FDA-regulated products are entitled to the non-infringement exemption which is provided to drugs under 35 U.S.C. § 271(e)(1) for testing which is conducted to obtain information to be submitted to the FDA for regulatory purposes. It is P&G's position that the Court of Appeals' decision is contrary to the clear wording of the statute, inconsistent with the intent of Congress, and should be reversed.

Notwithstanding that 35 U.S.C. § 271(e)(1) clearly specifies that otherwise infringing acts which are undertaken:

"... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture use or sale of *drugs*. . . ." (emphasis added)⁵

are exempt from liability for infringement, the Court of Appeals concluded that there was ambiguity in the statute. The Court then proceeded to conclude that it was the intent of Congress that the exemption should, in effect, extend to any product regulated by the Food & Drug Administration.

The Court of Appeals' decision came as a surprise to P&G. To P&G's knowledge, no one, either in commentary or during the legislative process, had ever read the statutory language of 35 U.S.C. § 271(e)(1) the way the Court of Appeals reads it, *i.e.*, to apply to all products (in addition to drugs and veterinary biological products) regulated by the

⁵ The statute was amended in 1988 to add the words "or veterinary biological products" after "drugs", however, the Court of Appeals stated that this amendment did not affect its analysis in the present case. Pet. App. 4a, Note 4.

FDA.⁶ In addition, Senator Orrin G. Hatch (principal author of the Senate Bill that enacted 35 U.S.C. § 271(e)(1) into law) and Representative Carlos J. Moorhead (primary floor manager of that legislation in the House of Representatives), in an *amicus* brief in support of Lilly's petition for certiorari in this case, expressed their view that Congress intended Section 271(e)(1) to apply only to drugs.

The pertinent legislative history is contained in two House of Representatives Committee Reports, Parts 1 and 2 of H.R. Report 857, 98th Congress, 2nd Sess. (1984), hereinafter "The Committee Reports". These reports show the statute was intended to be specific to drugs. The motivation for the enactment of Section 271(e)(1) was Congress' desire that generic copies of patented, approved drugs be made available to the public promptly upon expiration of the patents on the drugs (Committee Reports Part 1, at 14 and 15.)

Concurrently with the enactment of 35 U.S.C. § 271(e)(1), Congress enacted 21 U.S.C. § 355(j)(1),⁷ which provided for an abbreviated procedure for approving generic copies of previously approved drugs. Under this procedure, instead of the full safety and efficacy testing required for a new drug, only testing to demonstrate bioequivalence of the generic copy to the approved drug need be done.

⁶ Compare Goldstein, *The Drug Price Competition and Patent Term Restoration Act of 1984 Title II — Patent Extension Provisions*, 40 Food Drug Cosm. L.J. 363, 367 (1985) ("[W]hile the holding of *Roche v. Bolar* is reversed as to drugs, the implications of that case, as they relate to all regulated compounds other than human drugs, still remain in effect."); Flannery & Hutt, *Balancing Competition and Patent Restoration in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307 (1985) (Section 271(e)(1) "dose not include medical devices . . . food additives, color additives, or other related activities.")

⁷ 35 U.S.C. § 271(e)(1) and 21 U.S.C. § 355(j)(1) were both enacted into law as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

In the case of *Roche v. Bolar*⁸ regulatory testing of generic copies of patented drugs during the life of the patent had been held to be patent infringement, in that such testing was for "commercial purposes" and therefore not within the experimental use exception. Therefore, the only way for Congress to fully accomplish its objective of enabling generic copies of patented drugs to become promptly available upon patent expiration, was to grant an exemption from infringement for such testing of drugs.

The above-referenced Committee Reports are replete with statements indicating that it was Congress' intent that Section 271(e)(1) was to be specific to drugs. *See, e.g., id.*, Part 1, at 15 ("it is not an act of patent infringement for a *generic drugmaker* to import or to test a *patented drug* in preparation for seeking FDA approval" (emphasis added)); *id.*, Part 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval for *the drug*." (emphasis added)); *id.*, Part 1 at 45 ("The purpose of Section 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." (emphasis added)); *id.*, Part 2 at 6 ("... the other feature of the *drug* patent part of the bill is to statutorily modify the rules with respect to patent infringement"); *id.*, Part 2, at 29 (provision "permit[s] the limited testing of *drugs* while they are on patent" (emphasis added)). Similarly, the legislative history of the amendment expanding the exemption to certain veterinary products describes Section 271(e)(1) as a provision that "applies to *human pharmaceuticals*." S. Rep. No. 448, 99th Cong., 2nd Sess. 13 (1986) (emphasis added).

There is nothing in the legislative history to indicate that Congress intended this statute to affect patents on any type of product other than drugs. The Court of Appeals did not cite any language from the legislative history (because there is

⁸ *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).

none), which states in words or substance that FDA-regulated medical devices, food additives, color additives, and other non-drug products fall within the exemption of Section 271(e)(1). The Court of Appeals instead, reasoned that since 35 U.S.C. § 156, which provides for extension of the patent term for drugs, medical devices, food additives and color additives whose marketing has been delayed by regulatory review, was passed along with Section 271(e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984, it must have been Congress' intent that the infringement exemption of Section 271(e)(1) apply to medical devices (and food and color additives) as well as drugs (Pet. App. 7a).

B. The Court of Appeals Failed to Recognize the Regulatory Differences Between Drugs and Other FDA-Regulated Products, and Thereby Failed to Understand Why Congress Limited Section 271(e)(1) to Drugs, Notwithstanding The Granting of Patent Term Restoration to Drugs, Medical Devices and Food and Color Additives in 35 U.S.C. § 156.

The over-simplified reasoning by the Court of Appeals fails to take into account (as Congress surely did) the totally different regulatory considerations applicable to drugs on the one hand and to medical devices, food additives and color additives on the other. When enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Congress modified the procedures for regulatory testing of drugs, but not for medical devices, food additives or color additives, nor did Congress address any patent infringement issues relating to these procedures for these latter three types of products. It is expected that considerations relating to drug vs. medical device comparison will be thoroughly dealt with in Lilly's brief. The comparison of drugs vs. food additives and color additives will be dealt with here.

Approval of a new drug requires testing to establish proof of safety and efficacy. Such testing is very cumbersome and

expensive, especially with respect to efficacy, since efficacy must be established in clinical tests on humans afflicted with the illness for which the drug is indicated. Once a drug has been approved in this manner, the generic company can now obtain approval of its copy of the approved drug by testing the copy against the approved drug for bioequivalence. This is done by administering the generic copy to a limited number of human subjects (who usually do not have the illness for which the drug is indicated) and, in the same test, administering the previously approved drug to human test subjects. A determination is then made as to whether the rate and extent of absorption of the generic copy and that of the approved drug are equivalent. Cf. 21 U.S.C. § 355(j)(7) (definitions of bioavailability and bioequivalence). Upon submission of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of an abbreviated new drug application submitted pursuant to 21 U.S.C. § 355(j)(1).⁹

The main effect of Section 271(e)(1) in the context of drugs is to allow the completion of such bioequivalence testing of a generic copy of a patented drug prior to patent expiration so that marketing of the copy can begin promptly upon expiration of the patent on the originally approved drug. Although Section 271(e)(1) would also allow a non-patentee to undertake full safety and efficacy testing for drug approval of patented compounds which had not been previously approved for drug use, the ordinary practice of a non-patentee drug manufacturer is to copy a compound upon which the patentee has already obtained approval for drug use, and then obtain approval of the copy by bioequivalence testing. Drug testing that would involve infringement of a patent, but would not involve testing of a generic copy of a previously approved drug, would be extremely rare.

⁹ An alternative procedure for generic copies of some drugs approved after 1962 is the submission of a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b)(2).

The approval of food additives is provided for in 21 U.S.C. § 348. Under this statute a party wishing to gain approval for a new food additive files a petition with the FDA proposing the issuance of a regulation prescribing the conditions under which the additive may be used. The petitioner provides the FDA with pertinent data pertaining to the chemical identity of the additive, conditions of proposed use, intended physical and technical effect, methods to analyze for the presence of the additive in food, and data concerning the safety of the additive, Cf. 21 U.S.C. § 348(b)(2). See generally, J. O'Reilly, Vol. 1, *Food and Drug Administration*, Ch. 11 (1989 Supp.).

When a regulation is issued which governs the use of the food additive, any party may market its own product in conformance with the regulation, Cf. 21 U.S.C. § 348(a)(2); i.e., a copier of the approved product may market its copy without any requirement to obtain separate approval. Thus, in the case of a patented, approved food additive, the copier of the additive can begin marketing its copy promptly upon expiration of the patent without any requirement to obtain prior FDA approval. There is no need to conduct any testing for regulatory purposes during the life of the patent.

This is also true of color additives, which are regulated by listing and certification under 21 U.S.C. § 376, i.e., there is no requirement of a copier of an approved color additive to have its copy of the said additive approved before marketing it in accordance with the regulations governing use of the additive. If the additive is patented, the copier can begin marketing its copy promptly upon expiration of the patent.

It is readily apparent, therefore that the objective which Congress sought when enacting Section 271(e)(1), i.e., to provide a means by which copies of patented *drugs* would become available promptly upon expiration of the patent, is in no way applicable to food and color additives. This situation already existed with respect to food and color additives *prior* to the enactment of Section 271(e)(1).

The Court of Appeals' interpretation of the Section

271(e)(1) has a significant negative impact on the rights of patentees of food additive and color additive inventions. Under the Court's holding the generic copier, in addition to continuing to have the benefit of a completely "free ride" on the regulatory approval obtained by a patentee of a food or color additive product, will now also be permitted to conduct regulatory testing of the patented, previously approved, additive product to seek issuance of new or modified regulations to govern new or expanded uses of it. Also, non-patentees will be permitted to conduct testing to obtain food or color additive approval of patented compounds which have not previously been approved, which could then be sold in competition with other products of the patentee as soon as the relevant patent expires. Both types of testing during the life of the patent are abridgements of the exclusive rights of patentees to conduct commercially motivated research on their patented inventions during the patent term. An intent to abridge such valuable rights of patentees should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case.

It is erroneous to infer, as the Court of Appeals has done, that since 35 U.S.C. § 156 (providing extension of the term of patents on drugs, medical devices, food additives and color additives to compensate for time consumed in regulatory testing and review) was enacted into law along with 35 U.S.C. § 271(e)(1), it was the intent of Congress that exemption for infringement under Section 271(e)(1) should be applicable to medical devices, food additives and color additives as well as drugs. The two statutes involved entirely independent objectives. They were not "companions" as the Court of Appeals referred to them¹⁰. In order to satisfy the policy of

¹⁰ Section 271(e)(1) was enacted along with 21 U.S.C. § 355(j)(1) (abbreviated procedure for approving generic drugs) under Title I of The Drug Price Competition and Patent Term Restoration Act of 1984. 35 U.S.C. § 156 (patent term restoration) was enacted under Title II of the Act.

stimulating research in the fields of drugs, medical devices, food additives, and color additives, Congress deemed it necessary to compensate innovators for the time effectively lost from the patent term because of the need for regulatory testing and review. This was accomplished by enactment of 35 U.S.C. § 156. In order to satisfy the policy of hastening the availability of low cost generic copies of approved drugs to the public, it was necessary to provide for an abbreviated procedure for testing copies of approved drugs. Since regulatory testing during the life of the patent had previously been held in *Roche v. Bolar*¹¹ to be patent infringement, it was necessary for Congress to enact Section 271(e)(1) in order to exempt the regulatory testing of generic copies of drugs from infringement.

¹¹ *Id.* Note 8.

CONCLUSION

The Court of Appeals decision is erroneous. The Court's interpretation of Section 271(e)(1) significantly abridges the exclusive rights of patentees of medical devices, food additives and color additives, thereby reducing the incentive for innovation and investment in these important fields. An intent to abridge such valuable rights should not be attributed to Congress in the absence of a clear expression in the statutory language or in the legislative history. Such expression is lacking in both places in this case. The Court of Appeals decision should be *reversed*.

Respectfully submitted,

Ronald L. Hemingway

Counsel of Record

Richard C. Witte

Julius P. Filcik

The Procter & Gamble Company

Winton Hill Technical Center

6071 Center Hill Road

Cincinnati, Ohio 45224

(513) 634-5593

Counsel for Amicus Curiae

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

BRIEF OF
INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

STEPHAN E. LAWTON

Counsel of Record

ELISE V. NGUYENDUY

REED SMITH SHAW & MCCLAY

1200 18th Street, N.W.

Washington, D.C. 20036

(202) 457-6100

Attorneys for Amicus Curiae

Industrial Biotechnology

Association

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QUESTION PRESENTED

35 U.S.C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other federally-regulated, non-drug products?

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IN THE
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**On Writ of Certiorari to the United States
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**BRIEF OF
INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
AS AMICUS CURIAE IN SUPPORT OF PETITIONER**

Industrial Biotechnology Association ("IBA") submits this brief *amicus curiae* in support of Petitioner Eli Lilly and Company. It is accompanied by written consents from Petitioner and Respondent.

INTEREST OF AMICUS CURIAE

In the past sixteen years, dramatic new developments in the ability to select and manipulate genetic material have sparked unprecedented interest in "biotechnology,"

or the industrial use of living organisms.¹ Current industrial applications of biotechnology include the production of new drugs, vaccines, medical devices, foods and food enzymes, chemicals and dyes, industrial enzymes, and biopesticides. Nonproduct-oriented commercial applications include the use of microorganisms to degrade toxic waste and forensic applications such as DNA fingerprinting.

As the diversity of applications suggests, biotechnology "could have a major impact on industries throughout the world." U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis*, at 3 (Washington, D.C.: U.S. Government Printing Office, January 1984).

Beginning around 1976, many small entrepreneurial firms were formed in the United States specifically to build on the growing body of fundamental knowledge in molecular biology and to profitably exploit it. Furthermore, large established companies in a spectrum of industrial sectors expanded their research and development programs to include the new genetic techniques. Today, several hundred entrepreneurial and established companies are dedicated primarily to developing products using biotechnology.

Combined, U.S. industry is spending an estimated \$1.5 billion to \$2.0 billion annually in biotechnology research and development. U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: U.S. Investment in Biotechnology*, at 5 (Washington, D.C.: U.S. Government Printing Office, July 1988).

¹ "Biotechnology" includes "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific use." U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis* (Washington, DC: U.S. Government Printing Office, January 1984).

Amicus IBA is a trade association representing 82 large and small companies that use biotechnology to make new products. Collectively, its members represent a majority of the private sector investment made in biotechnology. IBA's member companies are listed in the appendix to this brief.

Many biotechnology companies are developing medical devices, especially the class of medical devices used to diagnose diseases and other biological conditions. According to the congressional Office of Technology Assessment, diagnostic tests are second only to human therapeutics as the area of primary research and development focus by biotechnology companies. *Id.* at 79. In addition, many of those that focus primarily on human therapeutics focus secondarily on medical diagnostics.

The primary targets of biotechnology research in the diagnostics field have been genetic and infectious diseases.² Advances in biotechnology-based diagnostics will afford improved and earlier detection of these diseases, leading to higher survival rates, reduced health care costs, and improved quality of life for patients. For example, the diagnostic tests used to protect our Nation's blood supply from the human immunodeficiency virus (HIV), which causes Acquired Immune Deficiency Syndrome (AIDS), are made using biotechnology. Other currently marketed biotechnology-based diagnostics include tests for detecting blood in the stool (an early warning of rectal cancer), tests for pregnancy and identifying the time of ovulation, and diagnostics for such diseases as ovarian cancer, cystic fibrosis, Huntington's disease, Duchenne muscular dystrophy, and hepatitis B. Clearly, it is critical to retain the incentives for producing important products such as these.

² Genetic diseases are those in which heredity plays either an exclusive or significant role. Infectious diseases are spread from person to person through exposure to a virus or bacteria.

These medical products use known chemical compounds or biological substances which would be impossible or prohibitively expensive to make without biotechnological inventions. Each of these products owes its existence to the strong incentive to invest in research and development which patents offer. These patented biotechnological inventions are broadly applicable in medical device design, development and manufacture, and are often several steps removed from the product which is actually sold. For example, some diagnostic devices use monoclonal antibodies to detect minute amounts of hormones or disease antigens in the blood. These antibodies are made possible through biotechnological innovations in cell biology, tissue culture and manufacturing processes which precede the use of the antibodies themselves.

Under the Court of Appeals' decision, each issued patent offers in effect a short-cut for companies which have made no investment at all in pioneering research. In many cases, the biotechnology company has deposited essential biological materials in support of its patent application. These deposits, which are virtually unique to the biotechnology industry, will now become available to unlicensed companies not when the patent expires but as soon as the patent issues. The copier of a patented invention will be able to manufacture its generic product using these raw materials without compensating the patent holder. This places the otherwise-infringing company at an unfair advantage because its product uses materials which are not merely equivalent to the patented product, but derived from the same biological source.

The decision of the Court of Appeals may substantially erode patent rights and adversely impact the biotechnology industry. Thus, IBA's members have a compelling interest in having this Court correct the erroneous decision below and restore the full scope of patent protection for medical devices and other non-drug products.

SUMMARY OF ARGUMENT³

The decision of the United States Court of Appeals for the Federal Circuit interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984,⁴ codified at 35 U.S.C. § 271(e)(1). It stated that the limited exemption from patent infringement under Section 271(e)(1) extends to medical devices, food additives, color additives, and other products regulated by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act.

The plain language of Section 271(e)(1) makes clear that it applies only to the products specifically identified therein, i.e., "drugs" and "veterinary biological products." The legislative history confirms this reading of the statute and unequivocally demonstrates that Congress intended the statute to apply only to drugs and veterinary biological products.

Nevertheless, the Court of Appeals inexplicably departs from both the plain words of the statute and Congress' expressed intent. Its misinterpretation of the statute belies its failure to recognize the important difference between drugs and non-drug products in their development and regulation. In expanding the limited scope of Section 271(e)(1), the Court seems to express its own policy choices instead of those of Congress. This judicial legislation is clearly improper. The decision below constitutes a serious error of law which should be corrected.

INTRODUCTION

This case presents a federal statutory question of potentially extensive adverse impact on innovation, research and development of federally-regulated products. Unless the Court of Appeals' decision is reversed, its

³ *Amicus* adopts the statement of the case set out in the brief of Petitioner Eli Lilly and Company.

⁴ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

application will significantly erode the rights of patent holders in the medical device industry as well as in other industries in which biotechnology is being used.

For the first time, otherwise-infringing competitors will be able to make, use and sell patented inventions before the patent expires in order to obtain federal regulatory approval. This outcome, in effect, rewards copiers with an unfair advantage even though they did not undertake the substantial risk and enormous expenses required to research and develop the inventions. The Court of Appeals' misguided decision runs counter to the goals of the patent system, which is established to encourage the development of new inventions. Undoubtedly, it will reduce incentives for pioneering innovation, technological creativity and business investment, all of which are essential to the biotechnology industry.

IBA respectfully submits that the Court of Appeals' erroneous interpretation will have a far-reaching application beyond products regulated by the FDA, to agricultural chemicals and other patented, non-drug products that are subject to regulation by the federal government. The language of Section 271(e)(1) refers to ". . . uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products" and thus may affect a broader range of products than medical devices (emphasis added).⁵

⁵ The Court of Appeals stated:

Accordingly, we hold that Section 271(e)(1) allows a party to make, use, or sell any type of "patented invention" if "solely" for the restricted uses stated therein.

Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989) (emphasis in original).

ARGUMENT

I. THE COURT OF APPEALS IGNORED THE PLAIN LANGUAGE OF THE STATUTE

This case raises traditional statutory interpretation issues. The relevant statute is a provision of the Drug Price Competition and Patent Term Restoration Act of 1984,⁶ codified at 35 U.S.C. § 271(e)(1). It states:

It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products* (emphasis added).⁷

It is well-settled that "[the] starting point for interpreting a statute is the language of the statute itself." *Consumer Product Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980); *Mallard v. U.S. Dist. Court for Southern Dist. of Iowa*, 109 S.Ct. 1814, 1818 (1989) ("Interpretation of a statute must begin with the statute's language.") When the terms of a statute are unambiguous, courts must regard the statute as conclusive. *United States v. James*, 478 U.S. 597, 606 (1986). Assertions of ambiguity do not transform a clear statute into an ambiguous provision. *TVA v. Hill*, 437 U.S. 153, 173 n.18 (1978).

The language of Section 271(e)(1) is plain and clear. The straightforward reading of this statute is that it creates an exemption from the general patent infringement provisions of 35 U.S.C. § 271(a) for use of "drugs" and "veterinary biological products" in very limited situations. The Court of Appeals, however, inexplicably

⁶ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁷ The statute initially referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" was added in 1988. Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

failed to effectuate this ordinary reading of the statute. Instead, it decided that the statute contained "ambiguous language" and used the excuse of nonexistent ambiguity to construe it to cover a wide range of non-drug products, including medical devices, food additives and color additives. This extraordinary conclusion is an outright distortion of the plain meaning of the statute.

The Court's interpretation of Section 271(e)(1) also departs from the reading of the statute by other courts as well as commentators. In the present case, the District Court and the Court of Appeals panel which denied Respondent's motion for a stay of the District Court's injunction read Section 271(e)(1) as limited to drugs. The only other court which has considered the matter reaches a similar conclusion. "[I]t is . . . clear that Section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories, Inc.*, 7 U.S.P.Q.2d 1562, 1565 (D. Del. 1988) (dictum).

Several commentators likewise agree that the statute "is limited to human drugs, and does not include medical devices, . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985). See also Fox & Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984*, at 178, 187 (1987).

II. THE LEGISLATIVE HISTORY CLEARLY EVIDENCES THE LIMITED, PRODUCT-SPECIFIC APPLICATION OF SECTION 271(e)(1)

In reaching its decision, the Court of Appeals violates another fundamental principle of statutory construction. If there is any doubt as to the meaning of a statute's language, courts must defer to the intent of

Congress. See, e.g., *Mackey v. Lanier Collections Agency & Service, Inc.*, 486 U.S. 825, 108 S.Ct. 2182, 2191 (1988). Just as it has misread the unambiguous words of the statute, the Court of Appeals has also misinterpreted Congress' expressed intent.

According to the Court, in enacting Section 271(e)(1), Congress intended to allow a party to make, use or sell any type of patented invention, provided the patented invention was used solely to develop information to submit to a federal regulatory agency. 872 F.2d at 406. IBA agrees with Petitioner that this holding is clearly a misinterpretation of the intent of Congress in enacting Section 271(e)(1).

A. In Enacting Section 271(e)(1), Congress Expressly Intended To Apply The Statute Only To Drugs

The intent of Congress to limit the infringement exemption solely to specifically-identified products is evident in the statute's language "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*" 35 U.S.C. § 271(e)(1) (emphasis added), as well as in its legislative history.

The background on the enactment of Section 271(e)(1) reveals that the purpose of the statute was to overrule the decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984). In *Roche*, the Court of Appeals interpreted under Section 271(a) that it was an act of infringement to use a patented drug, prior to the patent's expiration, for purposes related to obtaining FDA approval for a generic substitute to be sold after the patent expires. The *Roche* court clearly indicated the issue was specifically limited to drug testing:

The district court correctly recognized that *the issue in this case is narrow*: does the limited use of a pat-

ented drug for testing and investigation strictly related to FDA approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?

Roche, 733 F.2d at 861 (emphasis added).

Cognizant of this narrow holding of *Roche*, Congress indeed intended to restrict the infringement exemption under Section 271(e)(1) exclusively to drugs when it passed the statute in 1984:

In Section 202, Congress would provide that it is not an infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA pre-marketing approval of a drug. The purpose of the provision is to overturn the ruling in *Roche* That case held that Bolar infringed a patent owned by Roche when, during the patent term, Bolar used the patented substance to prepare a submission to the FDA for the purpose of enabling Bolar to market the drug after the patent expired.

H.R. Rep. No. 857, 98th Congress, 2d Sess., pt. 2, at 27, reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2711 n.18 (emphasis added).

The legislative history expressly provides that "the only activity which [would] be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 8, reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2692 (emphasis added). Other legislative commentary further evidences the congressional understanding that the *Roche* holding, and therefore the purpose of the legislation, was drug-specific:

The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a patented drug

product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement. Since the Committee's Subcommittee on Health and the Environment began consideration of this bill, the Court of Appeals for the Federal Circuit held that this type of experimentation is infringement.

In *Roche* . . . the Court of Appeals for the Federal Circuit held that experimental use of a drug product prior to the expiration date of a patent claiming that drug product constitutes infringement, even though the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.

Id. at 2678-2679 (emphasis added).

Yet, according to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all its ramifications" (872 F.2d at 406) and allow a party to make, use or sell any type of patented invention solely for experimenting and obtaining federal regulatory approval. There is simply no support for this interpretation.

This erroneous opinion evidences the Court's failure to properly review the legislative history of Section 271(e)(1) for guidance. While it correctly recognized that the statute was enacted to overrule the *Roche* decision, it failed to ascertain what Congress thought *Roche* meant and thus what Congress intended to overrule. Instead, the Court substituted its own interpretation of the meaning of *Roche*. In doing so, it completely ignored its own clear language in that case. As shown above, the Court specifically recognized in *Roche* that the case was limited to drugs. 733 F.2d at 861. Nothing in that decision supports the Court's conclusion that the *Roche* holding extended to all patented inventions subject to regulatory approval.

Also, it is noteworthy that the legislative history of Section 271(e)(1) is absolutely silent with respect to medical devices or other non-drug products. It offers no indication whatsoever that Section 271(e)(1) was intended to extend to these products. Given the far-reaching economic impact of such a sweeping change and Congress' concern with the constitutional ramifications of eroding patent rights,⁸ it is implausible that Congress would have made the change without providing the affected industries an opportunity to state their case.

B. The Court Of Appeals Incorrectly Relies On The Legislative History Of Other Unrelated Provisions Of The 1984 Act

The Court's decision was apparently influenced by the fact that the 1984 Act, which included Section 271(e)(1), also provided for patent term restoration for drugs, medical devices, food additives and color additives. See 35 U.S.C. § 156. The Court concluded that the most logical reading of the 1984 Act was that Congress intended to apply Section 271(e)(1) to medical devices, and presumably also food additives and color additives, as well as drugs. 872 F.2d at 406. Clearly, there is no rationale to predicate the interpretation of Section 271(e)(1) upon the fortuitous happenstance that the Act, which grants a limited infringement exemption for drugs, also provides patent extension rights for drugs, medical devices and other FDA-regulated products. The patent term restoration provisions are entirely unrelated to the creation of the narrow infringement exemption for generic drug testing. The court's conclusion, unsupported by the legislative history, again demonstrates its erroneous approach to issues of statutory interpretation.

⁸ The legislative history shows that both generic and innovator drug manufacturers had extensive input in the drafting of Section 271(e)(1). See, e.g., 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore).

"[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Congress expressed its intention clearly in the 1984 Act. When it intended to grant patent extension rights to certain inventions, it specifically identified them. See, e.g., 35 U.S.C. § 156(f). In that statute, Congress expressly included drugs, veterinary biological products, medical devices, food additives, and color additives. By contrast, in Section 271(e)(1), Congress expressly identified only drugs and veterinary biological products. In accord with the *Russello* principle, the Court must give effect to this disparate inclusion and exclusion. In enacting the 1984 Act, Congress clearly intended some provisions to apply only to drugs and some to apply to drugs, medical devices, and other products.

C. The Subsequent Legislative History Of Section 271(e)(1) And Other Provisions Of 35 U.S.C. § 271(e) Confirm Congress' Intent To Limit Section 271(e)(1) To Specifically-Identified Products

Congress' intent to limit Section 271(e)(1) to specifically-identified products is further supported by its subsequent actions regarding the statute. In 1988, when Congress decided to add similar limited infringement exemptions to another category of patented product, i.e., veterinary biological products, it did so by express amendment of Section 271(e)(1). See Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).⁹ This product-specific addition to Section

⁹ The legislative history of the 1988 amendment to Section 271(e)(1) further confirms Congress' intent to limit that statute to specifically-identified products, i.e., drugs and veterinary biological products.

This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal

271(e)(1) is irrefutable evidence that it was never Congress' intent in the 1984 Act (as amended in 1988) to include medical devices within the infringement exemption of that section.

Also, a review of other paragraphs of Section 271(e) confirms the product-specific application of Section 271(e)(1). When Congress created the limited infringement exemption for drugs, it provided offsetting protection for drug patent holders in the same section. 35 U.S.C. § 271(e)(2) establishes that it would be an act of infringement to submit new drug applications with the intention of obtaining marketing approval before patent expiration. 35 U.S.C. § 271(e)(4) sets forth remedies for such infringement. Congress granted similar protection to animal drug patent holders in the 1988 amendment to Section 271(e)(1). See 35 U.S.C. § 271(e)(2)(B). Thus, if Congress had intended to extend the application of Section 271(e)(1) to medical devices and other products, it is indeed illogical that Congress would have failed to confer the same protection on patent holders of those products. The fact that Sections 271(e)(2) and (e)(4) are clearly specific to "drugs" and "veterinary biological products" compels the conclusion that the related provision in 271(e)(1) is likewise specific only to drugs and veterinary biological products.

III. THE COURT OF APPEALS ENGAGED IN IMPROPER JUDICIAL LEGISLATION

As pointed out in the opinion of Circuit Judge Newman dissenting from the denial of a rehearing *in banc*, the Court of Appeals was legislating "without regard to the consequences for research and innovation or the public interest." *Eli Lilly and Co. v. Medtronic, Inc.*,

drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to human pharmaceuticals.

S. Rep. No. 448, 99th Cong., 2d Sess. 13 (1986) (emphasis added).

879 F.2d 849, 850 (Fed. Cir. 1989) (Newman, J., dissenting). Judge Newman observed that Congress, not the Court, is empowered to legislate. *Id.* at 851 (citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567, 579 (1886)). By relying on its erroneous reading of the statute and congressional intent, the Court has engaged in improper legislation in the guise of statutory interpretation. The judicial function, however, is to apply statutes "on the basis of what Congress has written, not what Congress might have written." *United States v. Great Northern Ry. Co.*, 343 U.S. 562, 575 (1952). The Court may not substitute its policy choices for those of Congress and rewrite the law. See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979) ("Under our constitutional framework, federal courts do not sit as councils of revision, empowered to write legislation in accord with their own conceptions of prudent public policy."). Nevertheless, the Court here seems to express its own view of applicable policy considerations. 872 F.2d at 406. Because of the wide range of products apparently now falling within the scope of Section 271(e)(1), the Court's decision will trigger a sweeping change in the patent law, which should properly be left to Congress.

IV. FUNDAMENTAL DIFFERENCES BETWEEN DRUGS AND NON-DRUG PRODUCTS PROVIDE PERSUASIVE REASONS FOR LIMITING THE INFRINGEMENT EXEMPTION TO DRUGS

In enacting Section 271(e)(1), Congress considered the constitutional ramifications of creating an exception to patent infringement. It was concerned with whether the law so eroded the exclusive rights of drug patent holders that it might result in an unconstitutional taking. After carefully reviewing those constitutional ramifications in the narrow context of bioequivalency testing, Congress concluded that the nature of the

interference was minimal.¹⁰ H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 30, *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2692. This focus on the limited nature of drug testing demonstrates Congress' recognition of the fundamental difference between drugs and non-drug products in their development and regulation. This case is a good illustration of the significant ways in which drugs differ from medical devices with respect to FDA testing.

To obtain FDA premarket approval, manufacturers of new drugs (both innovator and generic drugs) must submit data and information relating to the safety and effectiveness of the drug. See 21 U.S.C. § 355. Prior to 1984, there was no statutory provision pertaining to the requirements for gaining FDA approval of generic drugs. In Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, Congress amended the drug approval statute to allow approval of generic drugs on the basis of "bioequivalency" tests rather than the full clinical trials otherwise necessary for FDA approval of innovator drugs. See 21 U.S.C. § 355(j).

Under this procedure, the manufacturer of a generic drug is not required to conduct independent clinical tests. Instead, it need show only that the rate and extent of absorption of its product is equivalent to that of the innovator drug. See 21 U.S.C. § 355(j) (7) (defi-

¹⁰ The pioneering biotechnology industry does not agree with this characterization of the loss of patent protection. In fact, during congressional hearings on the issue, the research-based pharmaceutical industry submitted arguments that legislative reversal of the *Roche* decision would constitute an unconstitutional taking of property in violation of the Fifth Amendment to the United States Constitution. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Committee on the Judiciary*, 98th Cong., 2d Sess. 516-522, 741-753 (1984) (Statement of Norman Dorsen and Memorandum of Laurence H. Tribe).

nition of bioequivalency). Since the bioequivalency tests are typically performed in the generic drug manufacturer's laboratories with a limited number of healthy volunteers who are not charged for the drug,¹¹ this type of abbreviated testing does not involve sales of the infringing drug and therefore does not take potential customers away from the patented drug manufacturer during the life of the patent. As a result, Section 271 (e) (1) does not affect the ability of the manufacturer of a patented drug to command exclusive sales during the life of the patent.

There are no statutory abbreviated procedures available for establishing the safety and effectiveness of copies of innovator medical devices which have been required to undergo premarket testing¹² as there are for generic drug products. The "Abbreviated New Drug Application" provisions of Title I of the 1984 Act are undisputably applicable only to drugs and not medical devices. Clearly, Section 271(e) (1) must also be applicable only to drugs because these provisions are interrelated.

In contrast to drug testing, testing of non-drug products is not as well-defined or as simple. For example, to obtain FDA-required data, medical devices must be tested in a treatment setting. Development of data may, with respect to the more sophisticated devices such as CAT-scans, require purchases of the devices by medical institutions during the experimental stage. For other devices such as hip prostheses, clinical testing involves permanent implantation. Medical devices by and large cost much more than drugs.

¹¹ Volunteers who are ill will generally be used in bioequivalency tests for toxic drugs such as cancer drugs.

¹² Not all medical devices must undergo premarket testing. In 1976, Congress enacted a complex statutory scheme that includes differing types of regulation of medical devices based on their potential risks. See 21 U.S.C. § 360c *et seq.*

In this case, to conduct its investigational testing, Respondent marketed its generic medical device to be permanently implanted in patients, directly competing with the patent holder for potential customers during the period of the patent. Thus, unlike the bioequivalency testing of drugs, clinical testing of medical devices involves substantial sales of the device being tested and has significantly greater financial implications during the term of the patent.

These fundamental differences in testing procedures and approval requirements provide a persuasive reason for distinguishing between drugs and other patented inventions in Section 271(e)(1). Unfortunately, the Court below failed to recognize this critical difference, declaring that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." 872 F.2d at 406.

Under the Court of Appeals' interpretation of Section 271(e)(1), it is permissible to market an otherwise-infringing product as long as the marketing is for the sole purpose of developing clinical data necessary for regulatory approval. The very nature of medical devices and the market structure of the relevant industries make this interpretation particularly damaging to the innovators of those devices. By misreading the statute and legislative intent, the Court of Appeals seriously undercuts the value of patents. It effectively reduces patent terms and may in some instances nullify patent protection altogether. This clear error of law will have an adverse impact on individuals and companies who innovate, develop and market inventions, particularly medical devices, and ultimately on those who would use and benefit from such inventions.

CONCLUSION

For the foregoing reasons, the decision of the Court of Appeals for the Federal Circuit should be reversed.

Respectfully submitted,

STEPHAN E. LAWTON

Counsel of Record

ELISE V. NGUYENDUY

REED SMITH SHAW & McCLAY

1200 18th Street, N.W.

Washington, D.C. 20036

(202) 457-6100

Attorneys for Amicus Curiae

Industrial Biotechnology

Association

November 22, 1989

APPENDIX

APPENDIX

November, 1989

MEMBER COMPANIES
INDUSTRIAL BIOTECHNOLOGY ASSOCIATIONAMERICAN CYANAMID COMPANY
Wayne, New JerseyAMGEN
Thousand Oaks, CaliforniaAMOCO CORPORATION
Naperville, IllinoisANAQUEST
Division of BOC
Murray Hill, New JerseyAPPLIED BIOSYSTEMS, INC.
Foster City, CaliforniaBAXTER TRAVENOL LABORATORIES, INC.
Deerfield, IllinoisBIOGEN INC.
Cambridge, MassachusettsBIOSOURCE GENETICS CORPORATION
Vacaville, CaliforniaBIOTECHNICA INTERNATIONAL, INC.
Cambridge, MassachusettsBRITISH BIC TECHNOLOGY LIMITED
Cowley, Oxford
EnglandCALGENE, INC.
Davis, CaliforniaCALIFORNIA BIOTECHNOLOGY INC.
Mountain View, California

CARGILL HYBRID SEEDS
Aurora, Illinois

CELGENE CORPORATION
Warren, New Jersey

CENTOCOR, INC.
Malvern, Pennsylvania

CETUS CORPORATION
Emeryville, California

CHEMAP, INC.
South Plainfield, New Jersey

CHIRON CORPORATION
Emeryville, California

CIBA-GEIGY CORPORATION
Greensboro, North Carolina

CODON
S. San Francisco, California

COLGATE-PALMOLIVE COMPANY
New York, New York

COLLAGEN CORPORATION
Palo Alto, California

CONNAUGHT LABORATORIES, INC.
Swiftwater, Pennsylvania

COORS BIOTECH PRODUCTS COMPANY
Westminster, Colorado

CROP GENETICS INTERNATIONAL
Hanover, Maryland

CYTOGEN CORPORATION
Princeton, New Jersey

DNA PLANT TECHNOLOGY CORPORATION
Cinnaminson, New Jersey

DNX
Princeton, New Jersey

THE DOW CHEMICAL COMPANY
Midland, Michigan

E.I. du PONT de NEMOURS & COMPANY
Wilmington, Delaware

EASTMAN KODAK COMPANY
Rochester, New York

ECOGEN INC.
Langhorne, Pennsylvania

ELI LILLY AND COMPANY
Indianapolis, Indiana

ENZYTECH, INC.
Cambridge, Massachusetts

GENENTECH, INC.
S. San Francisco, California

GENETICS INSTITUTE, INC.
Cambridge, Massachusetts

GENEX CORPORATION
Gaithersburg, Maryland

GENSIA PHARMACEUTICALS, INC.
San Diego, California

GENZYME CORPORATION
Boston, Massachusetts

GIST-BROCADES INC.
Charlotte, North Carolina

GLAXO INC.
Research Triangle Park, North Carolina

W.R. GRACE & COMPANY
Columbia, Maryland

GRANADA BIOSCIENCES, INC.
Houston, Texas

HAZLETON BIOLOGICS, INC.
Herndon, Virginia

HOFFMANN-LA ROCHE INC.
Nutley, New Jersey

HOUSTON BIOTECHNOLOGY INC.
The Woodlands, Texas

IBF BIOTECHNICS, INC.
Savage, Maryland

IMMUNEX CORPORATION
Seattle, Washington

IMPERIAL CHEMICAL INDUSTRIES PLC
Millbank, London
England

INVITRON CORPORATION
St. Louis, Missouri

LIFECODES CORPORATION
Elmsford, New York

LUBRIZOL ENTERPRISES, INC.
Wickliffe, Ohio

MERCK AND COMPANY, INC.
Rahway, New Jersey

MICROBIOLOGICAL ASSOCIATES, INC.
Rockville, Maryland

MILES INC.
Elkhart, Indiana

MONSANTO COMPANY
St. Louis, Missouri

MYCOGEN CORPORATION
San Diego, California

RJR NABISCO, INC.
Winston-Salem, North Carolina

NOVO INDUSTRI OF NORTH AMERICA, INC.
New York, New York

ORTHO PHARMACEUTICAL CORPORATION
Raritan, New Jersey

PARKE-DAVIS
Pharmaceutical Research Division
Warner-Lambert Company
Ann Arbor, Michigan

PHILLIPS PETROLEUM COMPANY
Bartlesville, Oklahoma

THE PILLSBURY COMPANY
Minneapolis, Minnesota

PIONEER HI-BRED INTERNATIONAL, INC.
Des Moines, Iowa

THE PLANT CELL RESEARCH INSTITUTE, INC.
Dublin, California

PORTON PRODUCTS
Washington, D.C.

THE PROCTER & GAMBLE COMPANY
Cincinnati, Ohio

REPLIGEN CORPORATION
Cambridge, Massachusetts

SANDOZ PHARMACEUTICALS CORPORATION
East Hanover, New Jersey

SCHERING-PLOUGH CORPORATION
Madison, New Jersey

G.D. SEARLE & COMPANY
Skokie, Illinois

SEPRACOR INC.

Marlborough, Massachusetts

SERONO LABORATORIES, INC.

Norwell, Massachusetts

SMITHKLINE BEECHAM

Philadelphia, Pennsylvania

E.R. SQUIBB & SONS, INC.

Princeton, New Jersey

T CELL SCIENCES, INC.

Cambridge, Massachusetts

TRANSGENE

Paris

France

TRANSGENIC SCIENCES, INC.

Worcester, Massachusetts

TRITON BIOSCIENCES INC.

Alameda, California

THE UPJOHN COMPANY

Kalamazoo, Michigan

VIAGENE, INC.

San Diego, California

WYETH-AYERST RESEARCH

Radnor, Pennsylvania

No. 89-243

Supreme Court, U.S.

FILED

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CLERK

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

**BRIEF OF AMICUS CURIAE
INTELLECTUAL PROPERTY OWNERS, INC.
IN SUPPORT OF THE PETITIONER**

DONALD W. BANNER
HERBERT C. WAMSLEY *
INTELLECTUAL PROPERTY
OWNERS, INC.
1255 Twenty-Third Street, N.W.
Suite 850
Washington, D.C. 20037
(202) 466-2396
Attorneys for Amicus Curiae

November 24, 1989

* Counsel of Record

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IN SUPPORT OF THE PETITIONER**

INTEREST OF THE AMICUS CURIAE

Intellectual Property Owners, Inc. ("IPO") files this *amicus curiae* brief in support of petitioner Eli Lilly and Company on the writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered March 29, 1989.

IPO was founded in 1972 by a group of individuals who were concerned about the lack of understanding of intellectual property rights in the United States. Members include nearly one hundred large and medium size com-

panies and some smaller businesses and independent inventors who own patents and other intellectual property rights. Members of IPO's Board of Directors are listed in the appendix to this brief. IPO is a nonprofit association exempt from federal income tax under Internal Revenue Code § 501(c)(6).

IPO conducts a government relations program in Washington, D.C. IPO supports legislation to strengthen protection available under the U.S. patent, trademark, copyright, and trade secret laws. Enactment of such legislation helps IPO's members and strengthens incentives for innovation and investment in the United States, improving the country's industrial competitiveness.

The Court of Appeals decision, by expanding the patent infringement exemption of 35 U.S.C. 271(e)(1) beyond drugs and veterinary biological products, may well erode patent rights not only in the area of medical devices, which is the area of the petitioner's patents, but also in the areas of food additives, color additives, agricultural chemicals, and other drug and nondrug products that are subject to regulation by the federal government or may be subject to federal regulation in the future.

This would weaken U.S. patent protection for IPO members, contrary to IPO's commitment to advocating strong rights in patents. IPO seeks to safeguard the full measure of the patent system that gives vital incentives for technological innovation, creativity, and business investment.

SUMMARY OF ARGUMENT

The language of § 271(e)(1) is not ambiguous. The only reasonable construction is that when Congress said it was providing an exemption for "a patented invention . . . for uses . . . under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products", Congress meant patented inventions on drugs or veterinary biological products.

Assuming *arguendo* that there is ambiguity in the language of § 271(e)(1), the analysis of the legislative history by the District Court is persuasive. The Court of Appeals misinterpreted what Congress intended when Congress overruled *Roche Products, Inc. v. Bolar Pharmaceutical Co.*

Congress did not intend to overrule the *Roche* interpretation of 35 U.S.C. § 271(a) with respect to all types of patented inventions. The 1984 enactment of § 271(e)(1) and the 1988 amendment made exceptions to the overruling of *Roche* even for drugs and veterinary biological products. Congress did not overrule the *Roche* interpretation of § 271(a) with respect to agricultural chemicals regulated by the Environmental Protection Agency. Congress changed the impact of the *Roche* interpretation of § 271(a) only for drugs and veterinary biological products.

ARGUMENT

I. THE COURT OF APPEALS MISINTERPRETED WHAT CONGRESS INTENDED WHEN CONGRESS OVERRULED *ROCHE PRODUCTS, INC. v. BOLAR PHARMACEUTICAL CO.*

The Court of Appeals adopted an extraordinary interpretation of how Congress intended to alter the impact of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*¹ when Congress enacted § 271(e)(1). The Court of Appeals was incorrect in its holding that the infringement exemption of § 271(e)(1) applies to medical devices,² and the court's opinion stated an incorrect rationale that is broader than the holding.

¹ 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

² Pet. App. 3a. "Pet. App. 3a" refers to page 3a of the appendix to Lilly's petition for certiorari. IPO will refer to the appendix to the petition for certiorari on other occasions using this citation form.

The Court of Appeals viewed the issue as "... whether section 271(e)(1) is a limited exception, which applies only to drugs as the district court ruled, or applies generally to patented inventions..."³ According to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all of its ramifications".⁴ The Court of Appeals said Congress meant to allow a party to "make, use or sell *any type* of 'patented invention'", if for "the restricted uses stated therein".⁵

This reasoning is in error. Congress certainly did not intend to overrule the *Roche* interpretation of § 271(a) with respect to "any type" of patented invention. We are not aware of anyone proposing to Congress in 1984 that the *Roche* interpretation of § 271(a) should be amended to such an extent.

Section 271(e)(1) does not even cover all types of drugs and veterinary biological products. The 1984 version of § 271(e)(1) stated that it did not extend to an "animal drug or veterinary biological product". The 1988 amendment to § 271(e)(1), which extended coverage to certain veterinary biological products, excluded biotechnology-related animal drugs and veterinary biological products.

When § 271(e)(1) was enacted, Congress also had before it somewhat similar proposals affecting patent rights in agricultural chemicals regulated by the Environmental Protection Agency.⁶ Congress did not enact those pro-

³ Pet. App. 5a.

⁴ Pet. App. 7a.

⁵ Pet. App. 7a (emphasis in original).

⁶ *E.g.*, H.R. 5529, 98th Cong., 2d Sess. Congress subsequently has considered several other bills affecting patent rights in agricultural chemicals. Some of these bills have proposed to amend § 271(e) to extend it to agricultural chemicals. *E.g.*, S. 1516, 100th Cong., 1st Sess., § 2402, p. 167 (amendment to 35 U.S.C. § 271(e) covering pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act).

posals. Neither petitioner nor respondent advocates that § 271(e)(1) overruled the *Roche* interpretation of § 271(a) as it affects agricultural chemicals.⁷

IPO agrees that the 1984 law did not cover any products regulated by agencies other than FDA.⁸ IPO notes, however, that the Court of Appeals opinion can be read to extend the reach of § 271(e)(1) to agricultural chemicals and all other types of patented inventions regulated by *any* federal agency.

The language in § 271(e)(1) does not limit the section to FDA-regulated inventions. It covers "... uses reasonably related to the development and submission of information under a *Federal law* which regulates the manufacture, use, or sale of drugs or veterinary biological products" (emphasis added). If one refuses to accept the words "drugs or veterinary biological products" at the end of § 271(e)(1) as being limiting, as did the Court of Appeals, then the section arguably covers all federally regulated, patented inventions.

IPO points to the overbroad language in the opinion of the Court of Appeals only to illustrate that the opinion

⁷ Memorandum of Respondent Medtronic, Inc. in Opposition to the Motion of Intellectual Property Owners, Inc. for Leave to File Brief Amicus Curiae in Support of the Petition for Certiorari 2-3; see Petition for Writ of Certiorari n.12. The petitioner presents the question for review by this Court as whether the Court of Appeals has expanded the patent infringement exemption to all FDA-regulated products. Petition for Writ of Certiorari at i. The respondent contends the phrase "patented invention" in § 271(e)(1) covers drugs and "medical devices regulated by the Federal Food, Drug and Cosmetics Act. . .". See Respondent's Brief in Opposition to Petition for Writ of Certiorari at i.

⁸ The 1988 amendment of § 271(e)(1), expanding the section to cover certain veterinary biological products, includes subject matter regulated by the Secretary of Agriculture under the Virus-Serum-Toxin Act. See Pub. L. No. 100-670, Title II, "Patent Terms". Thus, § 271(e)(1) now covers some subject matter not regulated by FDA.

makes incorrect assumptions about §§ 271(a) and 271(e)(1). These assumptions were the foundation for the court's opinion.

Circuit Judge Newman dissenting from the denial of a rehearing *en banc*,⁹ argued that the Court of Appeals was legislating. Judge Newman observed that Congress, not the court, is empowered to legislate in matters affecting patent rights. Newman dissent, Pet. App. 13a, citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567 (1886).

II. THE PLAIN LANGUAGE OF THE STATUTE AND THE LEGISLATIVE HISTORY SHOW THE PATENT INFRINGEMENT EXEMPTION OF § 271(e)(1) IS LIMITED TO DRUGS AND VETERINARY BIOLOGICAL PRODUCTS

The Court of Appeals concluded that "ambiguous language" in the statute and "ambiguous statements in the legislative history" supported inclusion of at least medical devices, food additives, and color additives within the infringement exemption of 35 U.S.C. § 271(e)(1), in addition to drugs and veterinary biological products.¹⁰ As explained above, IPO believes the Court of Appeals opinion possibly extends even beyond FDA-regulated products, to agricultural chemicals.

IPO submits, however, that the plain language of the statute and the legislative history show the patent infringement exemption for drugs and veterinary biological products in § 271(e)(1) does not extend to medical devices or to any other type of patented invention.

⁹ Pet. App. 10a.

¹⁰ See footnote 5 of the Court's opinion, Pet. App. 5a. There are reasons for distinguishing between drugs and non-drug, FDA-regulated products. Lilly's petition for Certiorari sets forth the reasons, and they will not be repeated here. See Petition for Writ of Certiorari 14-18.

The opinion by the Court of Appeals did not analyze the arguments considered by the District Court. Judge Newman's dissent highlights the incomplete nature of the analysis by the Court of Appeals. Judge Newman summarized the District Court opinion as follows:

The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set forth in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs.

Pet. App. 11a.

The only reasonable construction of § 271(e)(1) is that when Congress said it was providing an exemption for "a patented invention . . . for uses . . . under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products", Congress meant patented inventions on drugs or veterinary biological products. The language is not ambiguous.

The respondent argues that "patented invention" means any type of invention that happens to be regulated under the same federal law that regulates drugs or veterinary biological products. This is a very strained construction. If airplanes and automobiles were regulated under the same federal law, Congress would not exempt airplane inventions merely by referring to all patented inventions falling under the law regulating automobiles.

Assuming *arguendo* that there is ambiguity in the language of § 271(e)(1), IPO submits that the analysis of

the legislative history by the District Court¹¹ is persuasive. The House Committee Report states several times that the purpose of § 271(e)(1) was to allow testing of generic drugs before the date of expiration of the patent.¹² The terminology used in the Federal Food, Drug and Cosmetic Act also supports the interpretation that when Congress said drugs and veterinary biological products, Congress meant drugs and veterinary biological products.

CONCLUSION

IPO urges the Court to reverse the ruling by the Court of Appeals for the Federal Circuit that the infringement exemption of § 271(e)(1) covers other patented inventions besides drugs and veterinary biological products.

Respectfully submitted,

DONALD W. BANNER
HERBERT C. WAMSLEY *
INTELLECTUAL PROPERTY
OWNERS, INC.
1255 Twenty-Third Street, N.W.
Suite 850
Washington, D.C. 20037
(202) 466-2396
Attorneys for Amicus Curiae

November 24, 1989

* Counsel of Record

¹¹ Pet. App. 19a.

¹² H.R. Rep. No. 857, 98th Cong., 2d Sess., pts. 1 & 2 (1984).

APPENDIX

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Upjohn Company
Kalamazoo, MI

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Attorney
Washington, DC

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Wilmington, DE

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Westinghouse Electric Corp.
Pittsburgh, PA

No. 89-243

Supreme Court, U.S.

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

**BRIEF OF AMICI CURIAE
ZIMMER, INC. AND
BRISTOL-MYERS SQUIBB COMPANY
IN SUPPORT OF PETITIONER**

DONALD O. BEERS
(Counsel of Record)
BARBARA J. DELANEY
DAVID E. KORN

ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 728-4901

*Counsel for Amici Curiae
Zimmer, Inc. and
Bristol-Myers Squibb Company*

Of Counsel:

TIMOTHY WENDT
PAUL DAVID SCHOENLE

ZIMMER, INC.
P.O. Box 708
Warsaw, Indiana 46580

November 24, 1989

QUESTION PRESENTED

Did the Federal Circuit err as a matter of law by expanding the limited patent infringement exemption found in 35 U.S.C. § 271(e)(1) beyond the two subjects specifically mentioned in that statute, namely "drugs" and "veterinary biological products," to encompass, and thereby to erode patent protection for, medical devices?

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-243

ELI LILLY AND COMPANY,
v. *Petitioner,*
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On Writ of Certiorari to the
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for the Federal Circuit

BRIEF OF AMICI CURIAE
ZIMMER, INC. AND
BRISTOL-MYERS SQUIBB COMPANY
IN SUPPORT OF PETITIONER

INTEREST OF THE AMICI CURIAE

Zimmer, Inc., a manufacturer of medical devices, and Bristol-Myers Squibb Company, its parent corporation (hereinafter referred to collectively as "Zimmer"), file this brief as *amici curiae* in support of the Petitioner, Eli Lilly and Company ("Lilly"). Lilly seeks reversal of the decision of the Court of Appeals for the Federal Circuit which expanded the limited patent infringement exemption found in 35 U.S.C. § 271(e)(1)¹ beyond the two subjects specifically mentioned in that statute, namely

¹ Section 271(e)(1) was added to the patent laws as part of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "1984 Act").

"drugs" and "veterinary biological products," to encompass, and thereby to erode patent protection for, medical devices and other nondrug products regulated by the Food and Drug Administration ("FDA"). *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989). This decision, if allowed to stand, will have potentially enormous adverse economic effects on the business of Zimmer and similarly situated manufacturers of medical devices.² More importantly, this decision would curtail innovation by all United States manufacturers of medical devices at a time when innovation is greatly needed to address the numerous health care problems of our aging population.

Zimmer respectfully submits that because it is a member of the medical device industry and manufactures patented products potentially affected by the Federal Circuit's decision, yet does not have a direct interest in the specific products being contested, it is in a position to offer a useful perspective to the Court on the question presented.

SUMMARY OF ARGUMENT³

The Federal Circuit's decision is at odds with the plain meaning of Section 271(e) (1) as manifested in the particular words and phrases Congress used for the provision. The decision is also inconsistent with Congress' intent. The legislative history is replete with references to the application of the exemption to drugs, yet contains no references to medical devices. The context in which the statute was enacted, after prolonged negotiations about, *inter alia*, patent infringement provisions, between gen-

² The medical device industry is of substantial importance to the United States economy, involving an estimated more than \$24 billion in shipments for 1989, with an international trade surplus estimated at \$1.3 billion. U.S. Dept. of Commerce, *U.S. Industrial Outlook 1989*, 32-1 (1989).

³ *Amici* adopt the Statement of the Issues and Statement of the Case included in the brief of Petitioner Lilly.

eric *drug* manufacturers and innovator *drug* manufacturers, also confirms Congress' intent to limit the scope of the provision to drugs. Lastly, the Federal Circuit's decision would significantly and unjustifiably expand the statute because of differences in the ways drugs and medical devices are tested and would therefore constitute judicial encroachment on the legislative sphere.

Zimmer requests this Court to restore the plain meaning of the statute by reversing the Federal Circuit's decision and limiting the scope of Section 271(e) (1) to its enumerated subjects—drugs and veterinary biological products.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION IS AT ODDS WITH THE PLAIN MEANING OF THE STATUTE

As recently amended, Section 271(e) (1) states:

It shall not be an act of infringement to make, use or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e) (1).⁴

⁴ The last clause of the statute originally referred only to "a Federal law which regulates the manufacture, use, or sale of drugs." The term "or veterinary biological products" and the last clause in the parenthetical were added by the Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988) ("1988 Amendment").

Congress' decision to amend Section 271(e) (1) to bring certain animal drugs within the ambit of that Section emphasizes the

Courts are bound by a statute's specific language when construing its provisions. *See, e.g., United States v. James*, 478 U.S. 597, 604-05 (1986). Under a straightforward reading of the statutory language, Section 271 (e) (1) grants a narrow exemption from patent infringement in certain circumstances where it is necessary to develop and submit information to obtain FDA approval for drugs and veterinary biological products.⁵ The Federal Circuit, however, has read the provision to grant an exemption from patent infringement not only for developing information necessary to obtain approval of drugs and veterinary biological products but also for developing information necessary to obtain approval of medical devices and a wide spectrum of other products.

The Federal Circuit's interpretation requires a strained reading of the plain language of the statute. To bring medical devices within the ambit of the statute, it is necessary to find that the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" is shorthand for the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Public Health Service Act of 1944, 42 U.S.C. § 262 (the other statute under which FDA approves some (biological) drugs). It is simply not credible that Congress used such shorthand, when it spelled out "Federal Food, Drug, and Cosmetic Act" and "the Act of March 4, 1913" (the Act regulating veterinary bio-

narrowsness of the original provision. The early legislative history of the 1988 Amendment confirms this interpretation. *See* S. Rep. No. 448, 99th Cong., 2d Sess. at 13 (1986), describing the proposed amendment:

This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to human pharmaceuticals. (emphasis added.)

⁵ As discussed in Section II, *infra*, both the legislative history of Section 271(e) (1) as enacted in 1984 and the discussions of commentators confirm that this reading is the common one.

logical products)⁶ in a parenthetical proviso a few lines earlier in Section 271 (e) (1).⁷

Respondent Medtronic, Inc. has suggested that the use of the term "patented invention" in the first few lines of Section 271(e) (1), rather than "patented drug," clearly signals that Section 271(e) (1) was intended to be applied to medical devices and certain other nondrug products. In fact, the term "patented invention" was used because Section 271(e) (1) applies not only to drug product patents but also to patents for drug compositions and patents for uses of drugs. Thus, the term "patented drug" would have been potentially unclear, whereas the term "patented invention" clearly covers all three types of drug patents. Moreover, the term "patented invention" is the term used in 35 U.S.C. § 271(a), the provision which Section 271 (e) (1) modifies.⁸

Where Congress intended the 1984 Act to apply to both drugs and medical devices, it explicitly said so. For example, Congress stated that the patent term extension provisions of the 1984 Act apply to products subject to a regulatory review period before commercial marketing or use. 35 U.S.C. § 156(a) (4). Congress then explicitly defined such a product as (a) a human drug product or (b) "[a]ny medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act." 35 U.S.C. § 156(f) (1). Had Congress in-

⁶ Act of Mar. 4, 1913 ("Virus-Serum-Toxin Act"), Pub. L. No. 62-430, 37 Stat. 832 (1913) (codified as amended at 21 U.S.C. §§ 151-158).

⁷ In the next provision of the statute, 35 U.S.C. § 271(e) (2), Congress again referred to the Federal Food, Drug, and Cosmetic Act by its full name, without resorting to shorthand.

⁸ Section 271(a) states that "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent."

tended for Section 271(e)(1) to apply to medical devices, it would have been similarly explicit.

Under a straightforward reading of the statutory language, then, Section 271(e)(1) grants a narrow exemption from patent infringement in certain circumstances where it is necessary to develop and submit information to obtain FDA approval for *drugs* and *veterinary biological products*. It does not grant an exemption for medical devices and other FDA-regulated nondrug products.

II. THE FEDERAL CIRCUIT'S DECISION IS INCONSISTENT WITH CONGRESS' CLEAR INTENT

Assuming for a moment that the plain meaning of Section 271(e)(1) is not clear, the Federal Circuit's interpretation of that provision nevertheless violates the well-established principle of statutory construction that courts are required to defer to the intent of Congress where doubt exists about the meaning of the words of a statute. See, e.g., *Mackey v. Lanier Collections Agency & Service*, 486 U.S. 825, 108 S. Ct. 2182, 2191 (1988). Courts may not rewrite legislation in accordance with their own conceptions of prudent public policy, even if the policy choices made by the legislature might appear to be parochial or less than even-handed. See, e.g., *United States v. Rutherford*, 442 U.S. 544, 555 (1979). By contrast, the Federal Circuit's decision seems to be based on its own view of possibly applicable policy considerations. See *Eli Lilly*, 872 F.2d at 406 ("No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation.").⁹

⁹ In fact, there is a persuasive reason why Congress would make this distinction. See discussion, *infra*, in Section III.

The legislative history of Section 271(e)(1) as enacted¹⁰ unambiguously demonstrates that Section 271(e)(1) was intended to apply only to drugs. Evidence of that intent can be gathered in two ways. First and most directly, Congress many times *said* that this provision applied to drugs. No one in the entire legislative process *ever* suggested that it would apply to medical devices or other nondrug products. Second, the negotiation and ultimate structure of the statute demonstrate that Section 271(e)(1) applies only to drugs.

A. The Direct Legislative Evidence Is Clear and Uncontroverted

The direct legislative evidence clearly indicates that Congress intended that the limited patent infringement exemption apply only to drugs. Two Committee reports were prepared on the 1984 Act, one by the House Committee on Energy and Commerce and one by the House Committee on the Judiciary. The Report of the Committee on Energy and Commerce stated, "The purpose of sections 271(e)(1) and (2) is to establish that experimentation with a *patented drug product*, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 45 (1984) (emphasis added). See also *id.* at 15 ("Finally, Title II [which contains what would become Section 271(e)(1)] provides that it is not an act of patent infringement for a *generic drug maker* to import or to test

¹⁰ It is appropriate to look at Congress' intent in 1984 in enacting Section 271(e)(1) because the original statute included both the disputed phrase "a Federal law which regulates the manufacture, use, or sale of drugs" and an explicit reference to the "Federal Food, Drug, and Cosmetic Act." As noted, the 1988 Amendment, which added the phrase "or veterinary biological products," does not change the analysis. To the contrary, that amendment confirms that Congress intended to limit Section 271(e)(1) to two specifically identified products, *i.e.*, drugs and veterinary biological products.

a *patented drug* in preparation for seeking FDA approval if marketing of the *drug* would occur after expiration of the patent.”) (emphasis added).

The Report of the Committee on the Judiciary described Section 271(e)(1) as permitting “a generic manufacturer [to] obtain a supply of a *patented drug product* during the life of the patent and conduct tests using that product.” H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 5 (1984) (emphasis added). The same Report subsequently referred to “provisions of the bill which permit the limited testing of *drugs* while they are on patent in order to assist in the preparation of an *abbreviated new drug application*.” *Id.* at 29. (emphasis added.) See also 130 Cong. Rec. H8708 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (provision will allow generic manufacturer to “obtain a supply of a *patented drug product* during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to the FDA for approval”) (emphasis added); *id.* at H8712 (statement of Rep. Kindness) (“this bill would provide that the *generic drug manufacturers* can start playing around with the *drug* on which the patent is about to expire within a year”) (emphasis added).

A statement made by Rep. Moorhead underscores this point. He criticized Section 271(e)(1) precisely because it differentiated between pharmaceuticals on the one hand and all other types of patented products on the other:

There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder.

130 Cong. Rec. H9143 (daily ed. Sept. 6, 1984).¹¹

¹¹ Congress’ intent is further elucidated by the *amicus* briefs in support of Lilly’s request for rehearing *en banc* in the Federal Circuit and in support of certiorari filed by Senator Hatch, the principal Senate author of the 1984 legislation, and Representative

The only legislative reference that has been cited to support the Federal Circuit’s decision in fact, on close analysis, confirms the statute’s focus on drugs. The House Report stated that:

The provisions of Section 202 of the bill [*i.e.*, the Section which, when enacted, would become Section 271(e)(1)] have the net effect of reversing the *holding* of the court in *Roche*.¹²

H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 27 (emphasis added).

The *Roche* court stated that the issue before it was limited to a narrow question, namely whether “the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute[s] a use which, unless licensed, the patent statute makes actionable?” *Roche*, 733 F.2d at 861. It then stated that the district court had “held” that it does not, and reversed that holding. *Id.*

B. The Context in Which Section 271(e)(1) Was Passed Demonstrates that It Applies Only to Drugs

The circumstances surrounding enactment of Section 271(e)(1) confirm that the narrow patent infringement exception was intended to be applied solely to drugs. The legislative history of the 1984 Act clearly reveals that Section 271(e)(1) was enacted by Congress as one part of a many-faceted compromise between *generic drug manufacturers* and *innovator drug manufacturers*. See,

Moorhead, a primary floor manager of the bill in the House. Senator Hatch and Representative Moorhead reiterate in their briefs that Section 271(e)(1) was intended to apply only to drugs. Rehearing Brief of Sen. Hatch and Rep. Moorhead at 2; Brief in Support of Petition for Certiorari at 3.

¹² The Report was referring to *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984).

e.g., 130 Cong. Rec. H9123 (daily ed. Sept. 6, 1984) (statement of Rep. Gore) (legislation "has been a very difficult and complex effort to strike a balance between the interests of consumers and generic drug companies, on the one hand, . . . [and] the innovators of new drugs").¹³

The 1984 Act was, in fact, a grand compromise in which statutory changes long sought by the two competing drug manufacturing interests and their respective supporters were passed together. The generic manufacturers, for their part, primarily sought an easier route to FDA approval of generic copies of innovator drugs once patent protection for those drugs had ended.

The Federal Food, Drug, and Cosmetic Act, prior to the 1984 Act, required that the generic manufacturer complete expensive and time consuming safety and effectiveness testing before a new drug application for the generic copy could be approved and the drug could be marketed. It was generally believed that the testing requirements did not make scientific sense. If it could be shown that the generic copy produced the same amount of the drug at the site of its action in the body at the same rate, it could be concluded that that drug would be as safe and effective as the innovator drug. Such a showing could be made by "bioequivalence" tests, in which the generic and innovator drugs were administered to a relatively small number of test subjects and blood samples were taken at set intervals and analyzed.

¹³ See also the following statements, all of which refer to the statute as a compromise between opposed drug company interests: 130 Cong. Rec. H8707 (daily ed. Aug. 8, 1984) (statement of Rep. Kastenmeier) (Act is a "carefully crafted compromise"); *id.* (statement of Rep. Waxman) (Act represents a "compromise among divergent and sharply differing interests"); *id.* (statement of Rep. Synar) (Act "comes after a long and hard and arduous compromise").

FDA had, administratively, developed a form of new drug application that dispensed with the need for full safety and effectiveness testing of generic drugs and permitted approval based on bioequivalence testing. FDA refused, however, to make that short form application, called an "abbreviated new drug application" ("ANDA"), available for drugs first approved after 1962. Generic drug companies thus sought legislation to permit use of ANDAs for copies of innovator drugs first approved after 1962.

Because the costs of full safety and effectiveness testing deterred generic companies from seeking approval of copies of innovator drugs first approved after 1962, the pre-1984 law tended to preserve the market monopolies of innovator drugs even after their patents expired. Innovator companies thus stood to lose economically from a change in the law that would permit use of ANDAs for post-1962 drugs.

Innovator companies had, however, their own interest in changing the law applicable to pharmaceuticals. Because they were required to perform lengthy testing of each new product, and then to wait for extended periods, sometimes many years, for FDA approval of their new drug applications after the testing was completed, the effective patent life applicable to their products after approval was often relatively short. Innovator interests sought restoration of patent time lost in the testing and approval process. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 17-18 (1984).

Title I of the 1984 Act provided what the generic companies had sought, *i.e.*, ANDAs for copies of post-1962 innovator drugs. Title II provided patent term restoration for the innovator companies. Each interest, of course, was actively involved in the negotiation of the opposing interest's title. Thus, Title I contains restrictions on the availability of ANDAs. See 21 U.S.C. § 355 (j) (3), (4). Title II contains limitations on length and

availability of patent term restoration. 35 U.S.C. § 156 (a), (c), (g) (4).

As supporters of the two sides negotiated, it became apparent that each also sought changes in the law of patent infringement. The innovator drug companies wanted FDA to be required to delay approval of ANDAs until valid patents applicable to the drugs covered by the ANDAs had expired. They also wanted notice whenever a generic company submitted an ANDA that might infringe a claimed patent. So there would be no question that litigation could begin at the point when an ANDA was filed with FDA, they wanted the act of filing an ANDA with intent to market during the patent period to be patent infringement. They wanted, in effect, an automatic 30-month preliminary injunction against ANDA approval if that infringement led to patent litigation. They wanted an opportunity to sue the generic company for patent infringement before the generic company could seek declaratory judgment and they wanted any declaratory judgment suit to be brought in the defendant's home district. Ultimately, innovator drug company interests obtained all of these concessions. See 21 U.S.C. § 355(j) (4) (B) (ii) (approval delayed until valid patent expires); 21 U.S.C. § 355(j) (2) (B) (notice); 35 U.S.C. § 271(e) (2) (B) (ANDA submission is patent infringement); 21 U.S.C. § 355(j) (4) (B) (iii) (30-month approval delay); 21 U.S.C. § 355(j) (4) (B) (iii) (restrictions on suits for declaratory judgment).¹⁴

Generic drug interests obtained concessions in exchange: Innovator companies were required to submit

¹⁴ In the 1988 Amendments, each of these changes was applied to animal drugs. See 21 U.S.C. § 360b(c) (2) (D) (ii) (approval delayed until valid patent expires); 21 U.S.C. § 360b(n) (2) (notice); 35 U.S.C. § 271(e) (2) (B) (submission of abbreviated new animal drug application is patent infringement); 21 U.S.C. § 360b(c) (2) (D) (iii) (30-month approval delay); 21 U.S.C. § 360b(c) (2) (D) (iii) (restrictions on suits for declaratory judgment).

and FDA was required to publish information about patents claiming innovator drugs so as to guide generic companies to potential drugs for copying. 21 U.S.C. § 355(b) (1). And under Section 271(e) (1), bioequivalence testing would no longer be considered patent infringement.¹⁵

None of these changes in the law of patent infringement applied to medical devices.¹⁶ It is simply not credible that Congress, in the midst of a carefully negotiated drug bill, without giving innovator device manufacturers the many concessions that had been made to innovator drug manufacturers, would have significantly undercut patent protection for innovator devices. It is even less credible that Congress would have done so without the prompting of anyone supporting makers of generic copies of medical devices,¹⁷ and that such a significant change in the law could have been made without any opposition from makers of innovator medical devices.¹⁸ Clearly, the Federal Circuit simply misapprehended Congress' intent on this issue.

¹⁵ The same concessions were applied to animal drugs in 1988. See 21 U.S.C. § 360b(b) (1); 35 U.S.C. § 271(e) (1).

¹⁶ There are provisions for FDA approval of certain types of medical devices that are somewhat parallel to the drug approval provisions. (Only so-called "Class III" medical devices require FDA premarket approval. 21 U.S.C. § 360e. See Section III, *infra*.) The 1984 Act did not, however, change the premarket approval requirements for medical devices in any way. The only change in the law applicable to some medical devices was the opportunity for patent term restoration, which also applied to color additives and food additives. 35 U.S.C. § 156(f) (1) (B).

¹⁷ The legislative history does not reflect any participation by proponents of easier market access for generic copies of medical devices in the debate on this statute.

¹⁸ Some innovator drug manufacturers with medical device subsidiaries were involved in the negotiations which led to the patent term restoration provisions of the 1984 Act. Bristol-Myers Squibb Company, Johnson & Johnson, and American Home Products, for example, are companies that have both drug and device subsidiaries. See, e.g., 130 Cong. Rec. S10,504 (daily ed. Aug. 10, 1984) (state-

Prior to the Federal Circuit's ruling, no one read Section 271(e)(1) as extending beyond drugs. In the instant case, both the district court and the Federal Circuit panel which initially denied Medtronic's motion to stay the injunction entered below pending appeal found that Section 271(e)(1) applied only to drugs. The only other court opinion to discuss the issue prior to the decision below stated that "[i]t is also clear that section 271(e)(1) applies only to drugs, not to medical devices." *Scripps Clinic & Research Foundation v. Baxter Travenol Laboratories*, 7 U.S.P.Q.2d 1562, 1565 (D. Del. 1988) (dictum).

Similarly, prior to the Federal Circuit decision, no commentator had ever read Section 271(e)(1) to apply to any product other than drugs.¹⁹ To the contrary, several commentators agreed that that provision "is limited to human drugs, and does not include medical devices . . . food additives, color additives, or other related products." Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 307-08 (1985); accord A. Fox & A. Bennett, *The Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984* 178, 187 (1987).

The legislative history of Section 271(e)(1), the circumstances surrounding its enactment, and the subsequent interpretations of the provisions by the judiciary and commentators all confirm that Congress intended for the narrow patent infringement exemption contained

ment of Sen. Hatch). There is no evidence that these companies expressed any views on the advisability of applying Section 271(e)(1) to medical devices. It is difficult to believe that such a significant effect on medical device innovation would have elicited no reaction from these major device manufacturers.

¹⁹ The 1988 Amendment has of course extended the statute's scope to animal drugs and veterinary biological products.

therein to be limited to drugs. The Federal Circuit's decision misinterprets that intent and should be reversed.

III. THE FEDERAL CIRCUIT'S DECISION CONSTITUTES JUDICIAL LEGISLATION WITH FAR REACHING RESULTS

The Federal Circuit's decision significantly expands Section 271(e)(1), producing effects never contemplated by Congress because of differences in the way drugs and medical devices are tested and regulated. This case provides a clear illustration of the dangers of judicial usurpation of Congress' role. Without hearings or Congressional debate, the decision below was taken without an understanding of the significant effects the extension of Section 271(e)(1) would inevitably have on the medical device industry—effects different from those applicable to drugs.²⁰

As noted, Title I of the 1984 Act allows the approval of generic copies of approved drugs on the basis of "bioequivalence" tests rather than the full safety and effectiveness trials otherwise necessary to justify FDA approval of a drug product. In a bioequivalence test, a generic drug manufacturer administers its generic copy and the innovator drug to a limited number of human subjects (who usually do not have the illness for which the drug is indicated)²¹ to determine whether the rate and extent of absorption of its drug and of the innovator drug are equivalent. Cf. 21 U.S.C. § 355(j)(7) (definitions of bioavailability and bioequivalence). Upon submis-

²⁰ The Federal Circuit not only acknowledged, but based its decision on, its inability to understand why Congress would treat drugs differently than medical devices in passing Section 271(e)(1). See *Eli Lilly*, 872 F.2d at 406 (quoted in Section II, *supra*).

²¹ Test subjects who are ill will generally be used in bioequivalence tests only for drugs (such as cancer drugs) which are too toxic to be administered ethically to persons who will not receive a benefit from their use.

sion of test results showing bioequivalence, and data concerning the chemistry, manufacturing, and labeling of its drug, the generic drug manufacturer may obtain approval of either an ANDA submitted pursuant to 21 U.S.C. § 355(j) or a "paper" new drug application submitted pursuant to 21 U.S.C. § 355(b)(2).

The main effect of Section 271(e)(1) in the context of drugs is to allow the completion of such bioequivalency testing prior to expiration of the innovator patent. Although Section 271(e)(1) would allow nonbioequivalence testing of generic drugs if that testing were designed to obtain drug approval, the ordinary route to approval of a copy of a patented drug would be through bioequivalence testing, not through full clinical trials. Drug testing that would involve infringement of a drug patent but would not involve testing of a generic drug would be rare.

Congress found that bioequivalence testing of generic drugs has a *de minimis* effect on manufacturers of patented drugs. Since bioequivalence testing generally does not involve treatment of patients or permanent use of the product, bioequivalence testing does not take potential customers away from manufacturers of patented drugs during the life of the patent. Moreover, bioequivalence testing does not allow generic manufacturers to profit from copying a patented drug during the life of the patent because, as a practical matter, bioequivalence testing is never the subject of requests for reimbursement of the costs of treatment of test subjects. Therefore, despite Section 271(e)(1), manufacturers of patented drugs continue to enjoy exclusive sales during the life of the patent.

In fact, Congress specifically addressed the question of whether Section 271(e)(1) would result in a significant diminution of a drug patent owner's property rights in his or her patents. Congress concluded that Section 271(e)(1) was constitutional because it would have a *de minimis* economic impact on the holders of patents on

drugs. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 30 (1984):

In this case the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval. Thus, the nature of the interference is *de minimus* [sic].²²

See also H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 46 (1984).

By contrast, no process equivalent to bioequivalence testing exists for medical devices.²³ Nor is there any FDA approval process for medical devices that can fairly be called equivalent to either the ANDA or the paper new drug application processes described above for drug prod-

²² See also *id.* at 8:

[T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.

As noted, bioequivalence is equivalence in the rate and extent of absorption of a drug. 21 U.S.C. § 355(j)(7)(B).

²³ In 1976, the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 540 (codified as amended at scattered sections of 21 U.S.C. § 301 *et seq.*), required premarket clearance, for the first time, for some medical devices. Because the definition of "device" covered a large category of products, ranging from tongue depressors to extremely sophisticated machinery, the statute provided for the division of medical devices into three classes. Class I devices were those that could be regulated without any type of premarket clearance or review by the FDA. Class II devices did not require premarket approval but were required to comply with performance standards should such performance standards be promulgated by the FDA. Class III devices required premarket approval. See 21 U.S.C. §§ 360c-360e. Medical devices on the market prior to 1976 and any device that could be shown to be "substantially equivalent" to such devices did not require premarket approval unless the FDA both classified them as Class III devices and required, by regulation, that such approval occur. See 21 U.S.C. §§ 360c(f), 360e(a)-(b).

ucts. If a device manufacturer wishes to make a "generic copy" of a device subject to the premarket approval requirement, the generic manufacturer must itself prepare all the safety and effectiveness data that will be necessary for approval of a premarket approval application for its generic copy. (Alternatively, it may petition FDA to "down-classify" the product, which could make the preparation of safety and effectiveness data unnecessary.)

Testing of medical devices also differs from testing of drugs. Many medical devices, in order to be tested to provide data to form a basis for approval, must be used in a treatment context. For example, hip replacements of the type produced by Zimmer must be implanted in patients in clinical trials of the devices. While such products are used investigational, they are also necessarily being used to treat the patients. A patient that receives a successful hip implantation during a clinical trial of a product made in violation of a patent will not later be available as a customer for the product of the patent holder.

Medical device companies may also recover their costs from investigational use of devices. Medical device regulations allow reimbursement for the costs of manufacturing, researching, developing, and handling a device while it is being tested. *See* 21 C.F.R. § 812.7(b) (1989). Companies thus commonly charge consumers and institutions for the experimental devices.

Moreover, the testing of a device may require not only its use in a therapeutic context but also its introduction to a significant part of the potential market for the device, a phenomenon not present in the drug context. For example, the sale of several expensive devices for which the number of potential customers is relatively small, such as the sale of diagnostic machines to hospitals, may satisfy the market demand for that device even prior to FDA approval. Of course, if it could be proven that a product was being used or sold for purposes other than

"for uses reasonably related to the development and submission of information under a Federal law," such use or sale would forfeit the protection of Section 271(e)(1). In many cases, however, perfectly legitimate use of a medical device investigational in an effort to develop necessary information to obtain approval of that device will result in both sale of the device, sometimes extensively, for therapeutic use in patients and the introduction of that device to and its sale to a substantial segment of the market.²⁴

Therefore, if the Federal Circuit decision is allowed to stand, copiers of medical devices will be permitted to sell their copies, in the context of investigations, prior to the expiration of applicable patents. Thus, manufacturers of medical devices will not continue to enjoy exclusive sales during the life of their patents. Because investigational use of drugs, on the other hand, does *not* involve sales of competing products, Section 271(e)(1), interpreted in accord with its intent, does not abridge the right of a drug patent holder to exclusive sales during the life of its patent.

Because of these differences in the way drugs and medical devices are tested, the Federal Circuit's decision would significantly expand the reach of Section 271(e)(1). The decision whether such a rewriting of the statute is appropriate should be left to Congress.

²⁴ Intraocular lenses are a good example of medical devices which are, to a great extent, marketed while investigational. Because of the rapid innovation in the intraocular lens field, it is not uncommon that, by the time a lens is approved, it is considered outdated.

CONCLUSION

For all the foregoing reasons, Zimmer respectfully requests this Court to reverse the Federal Circuit's decision.

Respectfully submitted,

DONALD O. BEERS
(Counsel of Record)
BARBARA J. DELANEY
DAVID E. KORN

ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036
(202) 728-4901

*Counsel for Amici Curiae
Zimmer, Inc. and
Bristol-Myers Squibb Company*

Of Counsel:

TIMOTHY WENDT
PAUL DAVID SCHOENLE

ZIMMER, INC.
P.O. Box 708
Warsaw, Indiana 46580

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In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

MOTION OF AMICUS CURIAE
NEUROMEDICAL TECHNOLOGIES, INC.
FOR LEAVE TO FILE THE ACCOMPANYING
BRIEF AMICUS CURIAE IN SUPPORT
OF PETITIONER
ELI LILLY

JOHN R. FEATHER
Counsel of Record
VADEN, EICKENROHT,
THOMPSON & BOULWARE
One River Way, Suite 1100
Houston, Texas 77056

Of Counsel
MALCOLM H. SKOLNICK
University of Texas Health Science Center
Neurophysiology Center
1343 Moursund Avenue
Houston, Texas 77030

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In The
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**MOTION OF AMICUS CURIAE
NEUROMEDICAL TECHNOLOGIES, INC.
FOR LEAVE TO FILE THE ACCOMPANYING
BRIEF AMICUS CURIAE IN SUPPORT
OF PETITIONER ELI LILLY**

Pursuant to Rule 36.1 of this Court. *Amici curiae*, Neuro-medical Technologies, Inc. (NMTI), respectfully moves this Court for leave to file the attached brief of *amicus curiae* in support of Petitioner, Eli Lilly and Company. Movants have been

unable to secure consent of Respondent.¹

NMTI is a small company developing innovative technology to apply transcranial electrostimulation therapy to relieve chronic pain, ameliorate stress and abate physiological symptoms in drug withdrawal syndromes. NMTI holds patents and is prosecuting further patent applications in the field of this technology. The devices and processes NMTI hopes to bring to commercial clinical use are subject to FDA approval.

This Court has granted a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit in *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989) interpreting 35 U.S.C. § 271(e)(1) to provide that it shall not be an act of infringement to make, use or sell a patented medical device solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of such device.

NMTI is not currently involved with any products of the type referred to in this case but is acutely aware of the chilling impact that the decision of the court below will have on innovation in research and development on medical devices. Further, NMTI has identified several companies conducting clinical investigations on processes which would potentially infringe NMTI patents in the field but for the erroneous decision of the Court of Appeals. Therefore NMTI has a strong interest in this Court's review of the holding by the court below and moves this Court for leave to file this brief as *amicus curiae* in this matter.

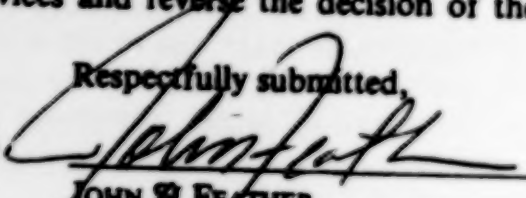
The accompanying *amicus curiae* brief sets out arguments that NMTI respectfully wishes to put before the Court which support the arguments made by Lilly in its Petition and agree

¹ *Amici curiae* obtained the consent of the petitioner to file its brief. On Monday, November 20, 1989, *amicus curiae* contacted counsel for the respondent Medtronic, Inc. pursuant to Rule 36.1 of this Court. Respondent's counsel declined to give its consent without first thoroughly reviewing the brief. Constraints of timely submission prevented such review if the *amicus curiae* had any expectation of filing the brief in this action. Therefore, this motion is required.

with the briefs submitted by other *amicus curiae*. Further, the subject brief advances additional reasons why this Court should distinguish drugs and devices and reverse the decision of the court below.

Respectfully submitted,

Dated: November 22, 1989


JOHN R. FEATHER

Counsel of Record

VADEN, EICKENROHT,

THOMPSON & BOULWARE

One Riverway, Suite 1100

Houston, Texas 77056

Of Counsel

MALCOLM H. SKOLNICK

University of Texas Health Science Center

Neurophysiology Center

1343 Moursund Avenue

Houston, Texas 77030

QUESTIONS PRESENTED

35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products."

The first question is that posed by Petitioner, Eli Lilly and Company:

Whether the Court of appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond "drugs" and "veterinary biological products" in the exact wording of the statute to encompass, and thereby to erode patent protection for medical devices, food additives, color additives and all other FDA regulated, nondrug products?

The second question presented is:

Whether, given the clear differences between the manner in which the FDA regulations enacted in Title 21 which specify the manner in which drugs as contrasted with devices must be investigated for regulatory approval, the meaning of "uses reasonably related to the development and submission of information" can possibly be reconciled and executed within the context of § 271(e)(1) as interpreted by the Court of Appeals?

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BRIEF FOR AMICUS CURIAE
NEUROMEDICAL TECHNOLOGIES, INC.
IN SUPPORT OF PETITIONER
ELI LILLY

Neuromedical Technologies, Inc. submits this brief of
amicus curiae in support of Petitioner Eli Lilly and Company.

INTEREST OF THE AMICUS CURIAE

NMTI a developer and manufacturer of medical devices files this brief in support of the position of Eli Lilly and Company ("Lilly") in this Court's review of the decision of the Court of Appeals for the federal Circuit in this matter. In that decision, issued on March 29, 1989, the circuit Court interpreted 35 U.S.C. § 271(e)(1) to apply to federally regulated medical devices as well as drugs thereby truncating the patent protection available to medical devices. This decision, if allowed to stand, will have serious and adverse effects on NMTI's activities in research, development and ultimate clinical application of its technology. Patent protection of proprietary technology is one of the most important elements in persuading investors that a technology is not only potentially useful but can be brought into the market place profitably. Vitiating of patent protection has a magnified and debilitating effect on an innovating company's acquisition of funding necessary to accomplish its goals.

ARGUMENT

I. A COPYING ENTITY'S USE OF FDA MANDATED
INSTITUTIONAL REVIEW BOARDS COULD ALLOW
REGULATION RELATED EXPERIMENTATION
WITHOUT INFRINGEMENT WITH NO DIRECT SUB-
MISSION TO OR SUPERVISION BY FDA.

The decision by the Court of Appeals in *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989) interpreted a provision of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417, 98 Stat. 1585 (1984)) to provide that it is not an act of infringement to make, use, or sell a patented medical device for uses reasonably related to the development and submission of information to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. That provision, codified as 35 U.S.C. § 271(e)(1), was enacted to permit limited testing of drugs during the term of an otherwise infringed patent. This testing was intended to demonstrate the bioequivalence of generic drugs prior to the termination of patented drugs with which said generic drugs might compete when the patent expires. The clear intent of the

law was facilitation of public access to cheaper generic drugs without extensive delay engendered by delaying testing until after patent expiration allowed testing to begin. Because of the differences in regulation of the investigation of experimental drugs and devices, the extrapolation of this intent by the circuit court's decision will encourage copying of patented medical devices and intrusions into their markets.

Since 1976, FDA regulations have required that studies involving investigation of medical devices performed on human subjects in institutions (including hospitals, nursing homes, mental institutions and prisons) be approved by an institutional Review Board (IRB) and be subjected to continuing review by the IRB. 21 C.F.R. §§ 50.1, 56.101, 812.1 (1989). All persons seeking exceptions for device testing involving human subjects must submit the studies for IRB review. 21 C.F.R. § 812.1 (1989). These studies must be reviewed and approved by an IRB whether subjects are institutionalized or not. 21 C.F.R. §§ 56.102(c), (d) & (f), 812.3(p) (1989).

The FDA may conduct on-site *procedural* reviews of IRBs and may inspect records of an investigation and sites where devices are used 21 C.F.R. § 812.145 (1989). These reviews are designed and conducted to determine whether an IRB is operating in accordance with its own written procedures as well as complying with current FDA regulations affecting IRBs.

A sponsor-investigator can obtain IRB review at an institution whose IRB conforms with FDA's regulations or by submitting the research proposal to an IRB created under the auspices of a local or State government health agency, community hospital, a medical school, a medical society, the State medical licensing board, an independent nonprofit group or other related organizations. The regulations allow sponsors of a study to form IRBs which can review clinical investigations conducted by investigators doing work for the sponsor. Establishment of commercial IRB organizations to review clinical investigations conducted by unaffiliated investigators is permitted by the regulations. FOOD AND DRUG ADMINISTRATION, FDA INFORMATION SHEETS, *NON-LOCAL IRB REVIEW, CLINICAL INVESTIGATORS UNAFFILIATED WITH AN INSTITUTION WITH AN IRB* (1984).

IRBs must maintain confidentiality of sponsor records, trade secrets and information of commercial interest. IRB members and staff should be aware that information submitted for review may be confidential, trade secret and of commercial interest and should recognize the need for maintaining a sponsor's confidentiality. FOOD AND DRUG ADMINISTRATION, FDA INFORMATION SHEETS, *SPONSOR-CLINICAL INVESTIGATOR-IRB INTERRELATIONSHIP* (1984).

Investigational devices are medical devices which are the object of clinical research to determine their efficacy or safety. 21 C.F.R. §§ 812.3(g), (h) (1989). An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device. 21 C.F.R. 812.1(a) (1989). Studies undertaken to develop safety and efficacy data for medical devices involving human subjects must be conducted according to the requirements of 21 C.F.R. parts 50, 56 and 812, protection of human subjects, governance by IRB's and granting of IDE's.

Investigational devices are determined to be either significant risk or nonsignificant risk devices. Examples of nonsignificant risk devices are: daily-wear contact lenses, lens solutions, antibacterial surgical garments, Foley catheters and incontinence devices. A significant risk device is one that presents a potential for a serious risk to the health, safety, or welfare of the subject. 21 C.F.R. § 812.3(m) (1989).

In addition to determining whether a study should be approved, IRBs reviewing clinical investigations of medical devices may also have to determine whether the device presents significant or non-significant risk to consenting subjects. 21 C.F.R. §§ 812.2(b)(1)(ii), 812.25(c), 812.66, 812.150(b)(9) (1989). The determination that a device presents non-significant risk is initially made by the sponsor and then passed to the IRB for review.

When the principal intent of the investigational use of a test article is to develop information about its efficacy or safety, submission of an IDE is generally required, however the law permits submission of an "abbreviated" IDE in some investigational sit-

uations. 21 C.F.R. § 812.2(b) (1989). Unless otherwise notified by the FDA, an investigation of a nonsignificant risk device is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements of the IDE regulations. These regulations require, in part, that IRB approval be obtained and maintained throughout the investigation and that informed consent be obtained and documented for all subjects. In these situations the ultimate decision to approve the clinical trial rests with the IRB reviewing the plan for the trial and under whose supervision the trial is being conducted. 21 C.F.R. § 812.62(a) (1989).

The IDE regulations allow sponsors to charge for an investigational device; however, the charge should not exceed an amount that is larger than necessary to recover the costs of manufacture, research, development and handling of the investigational device. A sponsor must justify proposed charges for the device, must state the amount to be charged and explain why the charge does not constitute commercialization. Sponsors are generally allowed to charge investigators for the investigational device, and this cost may be passed on to the subject. 21 C.F.R. § 812.7(b) (1989).

There is thus the possibility that a manufacturer could copy a patented device, convene his own IRB which could approve a clinical study that would be in perfect compliance with the FDA regulations. The copying manufacturer as sponsor of this clinical study could collect data on safety and efficacy of his device while charging fees calculated to return amounts balancing research, development and handling costs as well as expenses for implementing the device in clinical service. The subjects of this study will be removed from the patient pool available for purchase and use of the patented device. The copying sponsor while deriving revenue will also be establishing his share of the available market. There are no time limitations defined in the statute or addressed in the Circuit Court's discussion of its decision. Presumably, a copying manufacturer could initiate investigatory activity at any time during the life of the patented device being copied. The clinical test of the copy could run throughout the patent term of the copied device.

The possibility described in this scenario represents a severe blow to the ideals embodied in the patent statutes. The Court is respectfully requested to overturn the holding of the court below to prevent this emasculation of patent rights.

II. THERE ARE PERSUASIVE REASONS WHY CONGRESS CREATED AN EXCEPTION FOR NON-INFRINGEMENT UNDER § 271(e)(1) FOR DRUGS AND NOT FOR DEVICES.

The Drug Price Competition and Patent Term Restoration Act of 1984 included provisions for abbreviated testing of generic drug substitutes pursuant to regulatory approval. Recourse to abbreviated testing would enable more prompt marketing of generic substitutes after the expiration of the patented drug subject to substitution. The abbreviated testing calls for establishment of bio-equivalence and bioavailability as defined in 21 C.F.R. §§ 320.1(a), (e) and (f) (1989). There are profound differences in testing bio-equivalence and bioavailability of drugs and the requisite safety and efficacy for medical devices. As succinctly noted in the *amicus curiae* brief by Pfizer Hospital Products Group, Inc., "There is no equivalent abbreviated testing for 'generic' medical devices." Pfizer brief at page 5.

Conclusive data to secure regulatory approval of medical devices must be obtained in clinical trials involving human subjects. As indicated earlier, once a subject has been exposed in a trial testing a copying medical device, he is unlikely to be available as a repeat patient who would use the patented device. Conversely, the FDA regulations state that it is preferable to determine bioavailability using animal models and healthy human volunteers. 21 C.F.R. §§ 320.25(a)(1) and (2) (1989). Thus, bioavailability testing of a generic substitute drug would not ordinarily impact the market of a patented drug.

Additional important differences between drugs and devices include the fact that generic drugs are manufactured by a relatively few, large pharmaceutical and chemical companies. Inventorship and production of medical devices is much more diverse and covers a much broader scope of enterprise. The Circuit Court's decision will be particularly injurious to the small company, single product component of the medical device

spectrum. The greater scope of device functions and the greater breadth of diversity in device producers indicates a more severe impact of the patent deprivation and taking effects of the lower court's decision. Investors contemplating medical device development will choose to back ventures employing copied devices whose value has been demonstrated by the innovating patent holder rather than encounter more risk associated with newer but less proven devices which would have been required to be at least colorably patentably distinct before the decision in the court below.

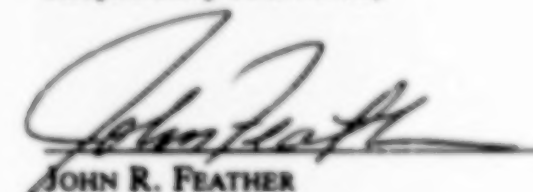
Aside from the fact stated by Petitioner and the other amici, that Congress only intended §271(e)(1) to apply to drugs, the profound differences between drugs and medical devices must be considered when contemplating the effects of the Circuit Courts ruling. We respectfully submit that both the development and the regulatory approval processes for devices are different than those for drugs. The interaction of these differences and the Circuit Court's decision will lead to adverse effects on innovating entities attempting to develop safe and effective devices for commercial clinical use. The negative effect of the Circuit Court's decision on the medical device industry and the public it serves combines with the obvious error committed in that decision to require reversal by this Court.

CONCLUSION

In removing threat of suit for infringement against generic drug producers attempting to hasten market entry, Congress has enacted a limited taking of rights from owners of drug patents. This limitation is reasonably defined by the relatively small number of generic drug producers and minimal market impact engendered in FDA approval of generic drugs. The enlargement of the scope of 35 U.S.C. § 271(e)(1) by the Court of Appeals to include medical devices affects vastly more patent owners, over potentially longer periods in patent terms and, because of the nature of the FDA regulation governing device testing, allows a copying device to erode a patented device's market. The harm potentiated by this decision exceeds the scope of the utility Congress sought to achieve in increasing the availability of less expensive drugs.

Therefore, *Amicus curiae* respectfully requests this Court review and reverse the decision by the Court of Appeals.

Respectfully submitted,



JOHN R. FEATHER

Counsel of Record

VADEN, EICKENROHT,

THOMPSON & BOULWARE

One Riverway, Suite 1100

Houston, Texas 77056

Of Counsel

MALCOLM H. SKOLNICK

University of Texas Health Science Center

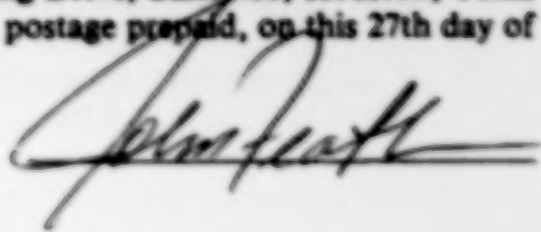
Neurophysiology Center

1343 Moursund Avenue

Houston, Texas 77030

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **Amicus Curiae Brief of Neuro Medical Technologies, Inc. and Certificate of Service** have been served on Philip Johnson, Esq. and Albert W. Preston, Jr., Woodcock, Washburn, Kurtz, Mackiewicz and Norris, One Liberty Place, 46th Floor, Philadelphia, PA 19103, Timothy J. Malloy, McAndrews, Held & Malloy, Ltd., 500 West Madison Street, 31st Floor, Chicago, Illinois 60606 and John Lynch, Arnold, White & Durkee, 750 Bering Drive, Suite 400, Houston, Texas 77057, via first class mail, postage prepaid, on this 27th day of November, 1989.

A handwritten signature in dark ink, appearing to read "John Lynch", is written over a horizontal line.

IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
v. *Petitioner,*
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals
for the Federal Circuit

BRIEF ON BEHALF OF PFIZER HOSPITAL
PRODUCTS GROUP, INC. AND PFIZER INC.
AS AMICI CURIAE

RUDOLF E. HUTZ
Counsel of Record
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
Wilmington, Delaware 19801
(302) 658-9141
*Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.*

Of Counsel:

PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd Street
New York, NY 10017

QUESTION PRESENTED

Did Congress, in enacting 35 U.S.C. § 271(e)(1), which specifically exempts from infringement certain activities involving "drugs or veterinary biological products," also exempt activities involving all other FDA-regulated, nondrug products, including medical devices?

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

 No. 89-243

ELI LILLY AND COMPANY,
v. *Petitioner,*
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals
for the Federal Circuit

BRIEF ON BEHALF OF PFIZER HOSPITAL
PRODUCTS GROUP, INC. AND PFIZER INC.
AS AMICI CURIAE

INTEREST OF AMICI

Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") are research-based manufacturers of medical devices and drugs. For many years, Pfizer has conducted research and development into such products for which it has received hundreds of United States Patents.

Pfizer's brief is being filed in support of the position of the Petitioner and urges this Court to reverse the decision below. Counsel for the Petitioner and for the Respondent have both consented in writing to the filing of this brief.

As a substantial patent owner, Pfizer has enjoyed the incentives offered by the United States Patent System in return for its research expenditures and innovation in the cure and alleviation of conditions destructive of the health and well-being of man. An important part of Pfizer's rights includes patents directed to medical devices which make up a significant portion of its sales in the United States.

In the decision below, the Court of Appeals for the Federal Circuit held that the infringement exemption set forth in 35 U.S.C. § 271(e)(1) applies to medical devices as well as to drugs and veterinary biological products. Unlicensed use and sale of medical devices were thereby authorized. Patents directed to a wide variety of lifesaving and quality-of-life-enhancing devices can now be practiced without the owner's consent, thereby reducing the reward, and hence the incentive, to undertake the enormous expense to develop and market new products.

Pfizer possesses a unique historical perspective as an innovator and marketer of both medical devices and drugs which enables it to speak knowledgeably regarding the differences in the approval processes and the heavy impact of the decision below on medical device innovation. Pfizer believes that this perspective and its experience in day-to-day dealings with the applicable Federal Laws governing sale of these products will assist the Court in better understanding the competing policies and statutory compromises intended by Congress when it enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act"). The information possessed by Pfizer is directly relevant to the reasons why Congress limited Section 271(e)(1) to drugs and did not extend its reach to include medical devices. The court below did not appreciate these distinctions when it concluded that there was no logical reason for treating drugs separately from medical devices, and it did not under-

stand the substantial effect its decision would have on the medical device industry.

ARGUMENT

The decision below should be reversed because it is based on a misreading of clear congressional intent as well as the decision, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984) ("Roche"), which Congress overruled when it enacted 35 U.S.C. § 271(e)(1). The 1984 Act simply does not say what the Federal Circuit claims it does, and the intent of the Congress behind the act belies the court's legally erroneous interpretation. The Federal Circuit decided an issue of pure statutory interpretation. Its decision evidences a lack of understanding of the FDA approval process for drugs as contrasted to medical devices and the competing policies and statutory compromises intended by Congress when it passed the 1984 Act.

I. CONGRESS DID NOT INTEND TO OVERRULE *ROCHE v. BOLAR* GENERALLY, BUT ONLY TO THE EXTENT NECESSARY TO PROMOTE OTHER POLICIES

The Federal Circuit properly stated that Section 271(e)(1) was enacted to overrule *Roche* (Pet. App. 5a).¹ The court, however, failed to recognize that the *Roche* holding (as contrasted with *dicta* and *underlying rationale*) was a narrow one relating to "the limited use of a patented drug for testing and investigation strictly related to FDA drug approval" (*Roche*, 733 F.2d at 861). Congress understood that *Roche's* holding was so limited when it considered and enacted Section 271(e)(1). See Part 1 at 45-46 and Part 2, at 8 and 27 of H.R.Rep.

¹ "Pet. App." refers to the Appendix filed by Petitioner, Eli Lilly and Company.

No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News 2647.²

In reaching its erroneous conclusion to expand the reach of § 271(e)(1) beyond its literal meaning and the narrow intent of Congress, the Federal Circuit cited no legislative history whatsoever and it failed to recognize that the 1984 Act was based upon a desire to promote two significant congressional policies, neither of which *per se* involved overruling *Roche*.

First, the 1984 Act contained provisions for patent term restoration for drugs, medical devices, food additives and color additives. Second, the 1984 Act authorized abbreviated testing procedures for regulatory approval of generic substitutes for patented drugs so that generic drug substitutes could be marketed promptly after expiration of patents covering the drug. These statutory provisions for expedited marketing of generic substitutes applied to drug products *only*. There were no comparable provisions for abbreviated testing for "generic" medical devices.³ Under the *Roche* holding, abbreviated testing procedures would constitute patent infringement, and so Congress had to make a very limited exception to the law of infringement to carry forward its second policy objective.

Without question, Congress intended 35 U.S.C. § 271(e)(1) to apply to drugs only because Congress, in enacting the 1984 Act, reasoned as follows: (1) patent term restoration for drugs, medical devices, food additives and color additives was, in and of itself, a desirable

² The narrow Congressional focus in § 271(e)(1) is confirmed by subsequent amendments and proposed amendments to this section which are product specific and would be unnecessary were the Federal Circuit's view correct (See, for example, Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988)).

³ The legislative history of the 1984 Act shows no significant input by the manufacturers of "generic" medical devices.

objective; (2) abbreviated testing procedures limited to generic substitutes of patented drugs to permit prompt marketing after patent expiration was also a desirable objective; and (3) in order to realize its second objective, 35 U.S.C. § 271 had to be amended (as in 35 U.S.C. § 271(e)(1)) for patented *drugs* inventions only.

II. THE APPROVAL PROCESSES FOR DRUGS AND MEDICAL DEVICES ARE DISTINCTLY DIFFERENT; UNLIKE DRUGS, THE IMPACT OF § 271(e)(1) IS SIGNIFICANT WHEN APPLIED TO MEDICAL DEVICES

Before new drugs can be marketed, they must receive premarket approval by the FDA, including a showing of safety and effectiveness (21 U.S.C. § 355). Prior to the 1984 Act, even generic copies of prior approved drugs generally necessitated submission of the manufacturer's own clinical data to obtain regulatory approval. In 1984, Congress established an abbreviated procedure for obtaining approval of such generic drugs (21 U.S.C. § 355(j))—the manufacturer must show only "bioequivalency" to an approved drug, i.e., that it has the same "rate and extent of absorption" into the blood stream. 21 U.S.C. § 355(j)(7)(B)(i).⁴

A test for "bioequivalency" typically involves tests on a limited number of volunteers, who do not have the disease for which the drug is intended. These drugs are often administered on a one time basis and do not remain in the volunteers' system after the effects have dissipated. The volunteers are not candidate customers for the patent owner's product, and they are not charged for the drug. The patent owner loses no sales through third party testing of this sort. Thus, the impact of such tests on the patent owner's commercial interests is minimal,

⁴ A generic manufacturer could conduct full clinical trials and submit its own data in seeking approval but given the faster and far less expensive "abbreviated" option, it is unlikely that any would do so.

and Congress determined the impact to be "*de minimis*" (H.R. Rep. No. 857, Part 2, at 30).

By contrast, there is no "abbreviated" procedure for medical devices. Compliance with premarket approval requirements for medical devices includes full-scale clinical trials. Patients with the underlying disease or condition are actually treated and, for many devices, this includes permanently implanting the device so that the treated patient is thereafter unavailable as a customer for the patent owner. Where a diagnostic machine is involved, particularly where the cost is high and the number of potential customers is small, each third-party investigational machine becomes a lost sale for the patent owner.

Manufacturers of investigational devices being tested for approval may charge for their use even though such sales are of products squarely within the scope of a valid patent owned by another (21 C.F.R. § 812.7(b)). The studies frequently involve the participation of leading physicians and medical institutions and such skilled participants are thus lost to the patent owner for his use in similar studies. The manufacturer of the investigational device may use these studies to enhance its reputation for innovation and inventiveness even though the device in question was invented by another and is literally covered by its valid patent.

In short, clinical trials by those who would be infringers but for the decision at issue can deny a medical device patent holder millions of dollars in lost sales and enhance the reputation of a competitor, yet the patent owner has no recourse. No such substantial economic impact occurs during bioequivalency drug testing, a fact recognized by Congress in its discussion of the 1984 Act. See H.R. Rep. No. 857, Part 2, at 8 and 27-30; *Id.* Part 1, at 46. The facts of this case are a perfect illustration of the significant harm caused the patent owner by im-

munizing "testing" activity from the reach of the law even though such testing is squarely within the claims of a patent the district court held was valid and otherwise enforceable. See Pet. App. 12a-13a.

III. THE DECISION BELOW ADVERSELY IMPACTS ON A SIGNIFICANT UNITED STATES INDUSTRY OF IMMENSE IMPORTANCE TO THE PUBLIC

Medical devices, as defined by 21 U.S.C. § 321(h) and 360(e) encompass a wide variety of products ranging from simple to very sophisticated machinery such as cardioverter defibrillators, orthopedic products, CAT-scans, x-ray and ultrasound machines, and other life-saving devices.

Research and development of such devices are extraordinarily expensive as are the studies necessary to approve such products for sale. Businessmen will not invest to bring these products to the market unless there is a reasonable assurance that a copiest cannot be rewarded at the expense of the innovator.

The effect of the Federal Circuit's opinion is to significantly devalue patent protection in the medical device field and, consequently, to provide a disincentive for innovation, technological development and investment which benefit the health and well-being of the public. The greatest loss will be to the patients who might have benefited from innovation and development that did not occur.

The need to encourage invention and innovation in this country has been expressed and documented by all segments of the economy, both public and private, and has received Constitutional recognition. Innovation in life-saving or life-enhancing medical devices should not be chilled by permitting copiests to wait for the innovator to spend time and money on developing and patenting medical devices and then to exploit and detract from the patentee's market in the face of a valid and otherwise enforceable patent.

The Federal Circuit's judicial legislation below has deprived the medical device industry of the opportunity to advise Congress of the direct adverse impact on them and the general public of applying Section 271(e)(1) to their products. See generally Pet. App. 11(a). The court below plainly did not appreciate this impact when it stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only . . ."

Given the prohibitions in the Constitution's taking clause, it is questionable whether Congress itself could have by law restricted a patent owner's rights as did the Court below. Most certainly, however, the rights possessed by owners of medical device patents cannot be taken away under the guise of statutory interpretation in the face of clear, contrary statutory language and congressional intent.

CONCLUSION

The decision of the Federal Circuit below, in an area where it has no special expertise, is a clear error of law. It will have a direct adverse impact on companies which innovate, develop, and market medical devices, and consequently on those who would benefit from such devices. The impact extends far beyond the parties to this case. Patent owners in this field now hold patents which cannot be enforced against unlicensed use, even though the unlicensed users reap significant benefits, both economically and business-wise.

This disincentive to innovation arises from a plain error in statutory construction. This clear error of law should be corrected by this Court.

Respectfully submitted,

RUDOLF E. HUTZ
Counsel of Record
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
Wilmington, Delaware 19801
(302) 658-9141
*Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.*

Of Counsel:
PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd Street
New York, NY 10017

IN THE
UNITED STATES OF AMERICA

WILLIAM J. BROWN

Defendant

vs.

UNITED STATES OF AMERICA
Plaintiff

U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

San Francisco, California

January 10, 1964

(1)

QUESTIONS PRESENTED

The only real question presented to this Court is whether this Court should remand this case to the United States District Court for an evidentiary hearing regarding whether LTV Steel Company, Inc. can afford restoration of the pension plans in question.

(II)

(III)

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In the Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-390

PENSION BENEFIT GUARANTY CORPORATION,

PETITIONER

v.

LTV CORPORATION, ET AL.

**ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

BRIEF OF RESPONDENT BANCTEXAS DALLAS, N.A.

STATEMENT OF THE CASE

The statement of the case is accurately presented by the Pension Benefit Guaranty Corporation in its brief.

SUMMARY OF ARGUMENT

This case concerns the Pension Benefit Guaranty Corporation's ("PBGC") efforts to reinstate pension plans of LTV Steel Company, Inc. ("LTV Steel") which were improvidently terminated. The District Court ruled that reinstatement of these improvidently terminated pension plans was appropriate if the PBGC could demonstrate, by providing a sufficient administrative record, that the plans would not be inevitably re-terminated. The District Court further ruled that the PBGC had not provided a sufficient administrative record to demonstrate the affordability of the pension plans

by LTV Steel. On appeal the Second Circuit affirmed in all respects the District Court's decision, 875 F.2d 1008.

BancTexas maintains that the PBGC had the right to restore the pension plans in question if such restoration will not inevitably result in retermination of the effected pensions plans. Thus, BancTexas Dallas, N.A. ("BancTexas") believes that the Second Circuit's decision should be affirmed and this case remanded to the District Court. At the District Court, the PBGC can quickly and easily supplement its administrative record by presenting evidence to the District Court to demonstrate that restoration of the terminated pension plans pursuant to Section 4047 of The Employee Retirement Income Security Act of 1974, as amended ("ERISA") was appropriate, that LTV Steel can afford the restored plans, and that subsequent retermination is not inevitable.

ARGUMENT AND AUTHORITIES

The PBGC posited two theories for restoration of the pension plans. First, the PBGC contended that utilization of a follow-on plan constituted a substantial abuse and justified restoration. The PBGC has fully elaborated on this theory in its brief.

Second, the PBGC concluded that restoration was warranted because the fortunes of LTV Steel had improved to the point where LTV Steel could now afford to make the required payments if the pension plans were restored. This "affordability" theory is also discussed by the PBGC in its brief. The District Court ruled, and the Second Circuit affirmed, that the PBGC could not prevail on its "abuse" theory because it was legally and factually unsound.

Likewise, the Second Circuit affirmed the District Court's finding that although the administrative record of the PBGC was not complete enough to support its affordability theory,

if the PBGC could supplement its administrative record to demonstrate affordability, restoration of the pension plans was proper pursuant to Section 4047 of ERISA. (875 F.2d 1008 at pg. 1020.)

The PBGC cannot prevail under either its abuse theory or its affordability theory unless it demonstrates that restoration of the pension plans will not inevitably lead to retermination and that LTV Steel can afford to service the restored pension plans. In order to prevail under its "abuse" theory, the PBGC must establish additional factors, including the inherent legal viability of the theory. Devotion of this Court's time to this academic question of "abuse" is an exercise in redundancy since restoration of the pension plans is appropriate if affordability is established and "abuse" cannot be established absent affordability.

BancTexas fails to understand why the PBGC does not simply present competent evidence directly to the District Court in support of its affordability theory.^o Everyone, including the PBGC, agrees that it would be improper for the PBGC to restore the pension plans if retermination of the pension plans is inevitable. Consequently, in order to act appropriately under Section 4047 of ERISA, the PBGC must be able to demonstrate that it is reasonably likely that the pension plans will not require retermination in the near future. Both the District Court and Second Circuit's opinion give the PBGC the opportunity to make such a determination either directly to the District Court or through an administrative process which will subsequently be reviewed by the District Court under an arbitrary and capricious standard.

^o Perhaps the PBGC's approach, and its current financial plight, can be attributed to the fact that the PBGC was modeled after the now defunct Federal Savings and Loan Insurance Corporation. See FN4 and text accompanying FN5, pgs. 3 and 4 of the PBGC Brief.

Instead of wasting this Court's time attempting to establish its abuse theory, the PBGC should present evidence directly to the District Court since it cannot prevail under either an abuse theory or an affordability theory unless it can establish affordability.

While the media has widely reported the District Court and Second Circuit's opinions as a victory for LTV Steel, BancTexas believes that ultimately the ruling is more beneficial to the PBGC since the ruling established the PBGC's right to reinstate the pension plans upon a simple showing that the fortunes of LTV Steel have improved to the point where LTV Steel can now afford to fund the reinstated plans. Mechanisms exist under the Bankruptcy Code which will allow the available cash flow of LTV Steel to be utilized to fund reinstated pension plans.

The Chapter 11 case of LTV Steel has been pending since June of 1986. For reasons which remain unarticulated, the PBGC has failed to supplement its administrative record regarding the restoration of the pension plans in question. In the meantime, creditors and other parties-in-interest have been stymied in their attempts to reorganize LTV Steel and its affiliates, including The LTV Corporation ("LTV"). Although some further delay is inevitable, neither the Bankruptcy Code nor ERISA contemplates protracted administrative review which will further delay the reorganization of LTV Steel and LTV. The PBGC has admitted its inability and unwillingness to balance the competing policies of the Bankruptcy Code and ERISA, PBGC Brief, Part III. To the extent possible, further delay should be avoided. Under these circumstances, further development of an administrative record by the PBGC would be superfluous since such action will be inevitably reviewed by the District Court which can and will balance the appropriate competing statutory policies. *See Midlantic National Bank v. New Jersey*

Department of Environmental Protection, 474 U.S. 494 (1986). The rights of all the parties, including the PBGC, LTV Steel, LTV and their respective creditors and other parties-in-interest will be best served by a direct presentation by the PBGC to the District Court of its evidence regarding affordability. No provision of ERISA prohibits such a procedure. Accordingly, the decision of the Second Circuit should be affirmed and this case should be remanded to the District Court for an evidentiary determination of the affordability issue.

CONCLUSION

WHEREFORE, PREMISES CONSIDERED, BancTexas respectfully prays that this Court affirm in all respects the Second Circuit's decision of May 12, 1989, and remand this case to the District Court for an evidentiary hearing on the issue of affordability.

RESPECTFULLY SUBMITTED,

ROBIN E. PHELAN

KATHRYN C. MALLORY

HAYNES AND BOONE

3100 NCNB Plaza

901 Main Street

Dallas, Texas 75202-3714

(214) 670-0550

January 1990



Harborview Medical Center

325 NINTH AVENUE
SEATTLE, WASHINGTON 98104
206/223-3000

April 1, 1988

Judge William Ditter
Federal District Court
Eastern District of Pennsylvania
601 Market St.
Philadelphia, Pennsylvania 19106

Dear Judge Ditter:

RE: CPI vs Medtronic lawsuit

I am writing to you as a concerned physician regarding the welfare of my patients. I hope to reveal to you how the financial scrapping of two medical device companies (Medtronic and CPI) ignores the very real human issues at hand.

I really don't know what transpired in the lawsuit between CPI and Medtronics from the viewpoint of patent rights, nor do I care. From my perspective, it doesn't matter who has the patent rights or who makes the most money from these devices. I do, however, care a great deal when legal business decisions prevent me from taking the very best care of my patients as possible. If I am legally prevented from using the new Medtronic device, I must then knowingly provide substandard care for my patients. This places me and others like me in a medically and ethically untenable position.

As an academic physician with extensive experience in the care of patients with life-threatening heart rhythm disorders, and as a physician and scientist who has extensive experience in the use of both the CPI and the Medtronic defibrillation systems, it is clear to me that many of my patients will suffer and some will die needlessly because I am forced to limit my therapies to the one provided by CPI. These two devices are no more alike than sulfa and penicillin are alike; sulfa and penicillin are both antibiotics but they serve different roles. The CPI AICD and the Medtronic PCD are both devices that treat heart rhythm disorders but their capabilities are very seriously different.

In short, one company's desire to have a monopoly on implantable defibrillators (i.e., CPI) subjects we physicians and our patients to limited therapeutic alternatives and forces us to use a product that isn't as well suited to patient care as another may be. On a very human level, it is important to recognize that the proceedings by CPI have already seriously and adversely affected a 55-year-old woman, Lauretta Olmstead from Seattle, Washington, in whom I was hoping to use the considerably smaller and much more appropriate Medtronic device. I hope to impart to you why more is at stake than just corporate patents and corporate income by relaying some background history regarding this woman to you. Mrs. Olmstead suffered an episode of sudden death due to ventricular fibrillation and was fortunate enough to be resuscitated by her husband and by paramedics. Having had one episode of sudden death aborted does not, however, spare her from recurrent episodes. In fact, she has a 30% risk of dying if nothing were to be done to prevent another cardiac arrest. To prevent another cardiac arrest, however, requires an automatic defibrillator. The only one available (legally) for Mrs.

Olmstead is the CPI automatic defibrillator which, however, is a poor second choice in this patient compared to the Medtronic device that is ideally suited to Mrs. Olmstead for two reasons: first, the Medtronic unit is much smaller than the CPI unit which is a crucial consideration in this tiny 75 lb woman and, second, the Medtronic unit is able to prevent the need for shocking her heart while the CPI unit is not. As such, I was hoping to implant it in her on March 24, 1988. However, I've had to cancel her surgery twice because of the legal proceedings as I was waiting for the case to be resolved before I could use the newer Medtronic unit. When I was told by Medtronic that I couldn't legally insert the device, I was astounded. The word "astounded" is overworked and often used as a hyperbole, but it nonetheless accurately represents my response as well as the response of my patient, her husband, and her daughters. I knew and they knew that I had a way to help my patient but I was prevented from doing so by greed on the part of a corporation.

As it turned out, after I was told I could not use the new Medtronic unit, I reluctantly implanted the 200 cc squarish CPI device in her tiny abdomen on March 28, 1988 rather than the smaller, rounded 103 cc Medtronic device. This was no trivial issue. I've enclosed photos of this woman's belly taken in the operating room to make my point. I've drawn on her skin with surgical ink along the lower margins of her rib cage and the upper margins of her hip bone to emphasize to you how little room there is in her abdomen. As you look at these photos, you need to be aware that the abdominal anatomy prevents insertion of these devices in the middle of the abdominal wall because of a dividing raphe and the umbilicus. They must be inserted to the right or to the left of the midline and umbilicus. Because these devices must be inserted either to the right or to the left of the umbilicus they must also fit between the lower rib margin and the hip bone. In this woman, there literally is no room for a comfortable implantation of the CPI unit; by inserting the CPI unit in her, we had to jam it between her rib cage and her hip bone. As a consequence, the CPI unit was so tightly inserted that it prevents her from comfortably bending over because the metal canister of the CPI unit is forced into her bony hip by her ribs each time she bends at the hip. Imagine having the choice between no defibrillator (and the resultant lack of protection from sudden death) and a defibrillator that jams into your ribs every time you bend over, go to the bathroom, sit down to eat, or have sex. By using the much smaller Medtronic device, we could have avoided the discomfort and limitations of motion the CPI device created.

A second and equally important consideration in Mrs. Olmstead's case is the fact that the Medtronic device can prevent the use of a painful shock. High voltage electric shocks is the only way the CPI device can stop her life threatening heart rhythm problem. The Medtronic device, on the other hand, can actually avoid the need for these painful shocks by a technique called "rapid ventricular overdrive pacing" which can stop her ventricular tachycardia before it requires a high voltage shock.

Judge Ditter, Mrs Olmstead's story is not unique to me or my colleagues around this country who specialize in the care of such difficult patients. There are many like her where the Medtronic unit would be a more safe, effective and less painful way of protecting the patient from sudden death. For example, the accuracy of detection of serious arrhythmias by the CPI device is not failproof. Another one of my patients, Wesley Ray, is only one of 18 patients who have been

inappropriately shocked by the CPI device. Mr. Ray was shocked 4 times for a relatively benign heart rhythm problem called atrial fibrillation because of faulty detection circuitry of the CPI device. The Medtronic unit, on the other hand, has a very clever way of discriminating between the relatively benign rhythm problems of atrial fibrillation and the more serious problems of ventricular tachycardia and ventricular fibrillation. It would be unfortunate for our patients to be deprived of the Medtronic device's capabilities because of capitalistic sophistry from a competing business.

Mrs. Diana Tucker, whose personal letter and photo of her abdomen is enclosed, illustrates yet another reason why business interests should not interfere with the best medical care possible. She had the need for both a regular pacemaker as well as an automatic defibrillator and, unfortunately, had to have two surgeries and two medical devices implanted when a single device, the Medtronic unit, would have done the job for her quite well. Unfortunately, because I was legally prevented from inserting the Medtronic device, she now suffers from having two devices.

As a physician deeply dedicated to the well being of my patients, I am abhorred by what has happened. I have used the CPI device for the 8 years it has been available and have been grateful for it and for Dr. Mirowski's contribution. But, my first allegiance is to my patients and not to CPI, Medtronic or Dr. Mirowski. If I know I can take care of my patients better with newer technology, then it is incumbent upon me to do so. From my perspective, the incredible greed of CPI has callously sacrificed the welfare of human beings for a profit. The whole proceeding is tantamount to saying that we shouldn't allow progress and improvements in health care nor should we allow patients to live longer and better because it will hurt the profit margin of a company (CPI).

Please allow me to do what is best for our patients by giving me access to state of the art medical technology provided by Medtronic. I'd be more than pleased to answer any questions you may have. You also can feel free to talk to any of my patients if it will help you.

Respectfully yours,

Gust H. Bardy

Gust H. Bardy, M.D.
Assistant Professor of Medicine
University of Washington
Associate Director, Clinical Electrophysiology
Director, Cardiac Pacing
Harborview Medical Center
Tel. (206) 223-3215

GHB:ltk-3473A

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF PENNSYLVANIA

J. WILLIAM DITTER, JR.

JUDGE

8814 UNITED STATES COURT HOUSE

INDEPENDENCE MALL WEST

PHILADELPHIA, PA 19106

597 9640

April 13, 1988

Gust H. Bardy, M.D.
Director, Cardiac Pacing
Harborview Medical Center
325 Ninth Avenue
Seattle, Washington 98104

Dear Dr. Bardy:

I have read and reread your very interesting letter of April 1, 1988. I hope you will try to understand this response.

When the delegates to the Constitutional Convention met in Philadelphia in 1787, they included in the document they drafted a provision "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." After the constitution was ratified, one of the first acts of the Congress in 1790 was to enact laws for the protection of inventors and authors. Over the years, there have been many revisions to the original patent act, but the theory remains the same: society is best served by encouraging invention and the only way to encourage invention is to provide a means for the inventor to profit from his labors.

I tell you all this because when I became a judge, I took an oath to support and defend the constitution and the laws of the United States and to do equal right to all persons.

That brings me to your letter. Stripped to its essentials, your letter asks me to forget the wisdom of the patent system, ignore the constitution and the laws of the United States, accept evidence from you without your being subjected to cross-examination, and act upon that evidence without any opportunity for rebuttal from CPI.

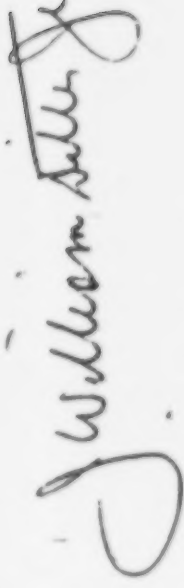
April 13, 1988

Dr. Bardy:

-2-

Doctor, I know that you have the best interests of your patients in mind. Still, I am a little surprised when you say that you do not know what transpired between CPI and Medtronic and that you do not care. While that may be your way of expressing your great concern for your patients, the fact remains that the suit is a matter of great consequence to the entire medical profession, those who are medical inventors, those who are medical investors and thus make invention possible, and society as a whole. Although I think it might have been a little fairer on your part to point out to me that you are one of Medtronic's investigators, I commend you for your concern for those who have come under your care. I hope you will understand, however, that my duty is not only to them but to the constitution and laws of the United States as well. Congress has not seen fit to treat the inventors of medical devices with less deference than it treats those who invent trivial and comparatively unimportant devices. Perhaps Congress should do so, but until that time I must interpret the present law.

Yours sincerely,



JWD:RMC

16
No. 89-243

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit**

**BRIEF OF AMICUS CURIAE
VENTRITEX, INC.
IN SUPPORT OF RESPONDENT**

GEORGE H. GERSTMAN
GERSTMAN & ELLIS, LTD.
Attorney for Amicus Curiae
2 North LaSalle Street
Suite 2010
Chicago, IL 60602
(312) 263-4350

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INTEREST OF AMICUS CURIAE

Ventritex, Inc. has obtained letters from both Petitioner and Respondent consenting to the filing of this *amicus* brief supporting Respondent. The letters have been filed with the Clerk.

Amicus Ventritex, Inc. is the manufacturer of an implantable defibrillator that is presently being clinically tested pursuant to an investigational device exemption (IDE) from the Food and Drug Administration. Ventritex's defibrillators were not manufactured or implanted until the original seventeen-year period of Eli Lilly's '757 patent had expired and the patent was in its extended term.¹

Ventritex was founded in 1985 through financing via private placement. Ventritex is composed of a number of individuals who are experts in the medical device field, and were previously employed in similar medical device endeavors. Since the founding of Ventritex, over 15 million dollars has been invested in the company. An additional five million dollars is presently being sought via private placement for use in manufacturing defibrillators for the clinical trials and for conducting the clinical trials. All of the investment in Ventritex to date relates to the research and development of its improved implantable defibrillator which is now in clinical trials.

Ventritex's implantable defibrillator is superior in numerous respects to the implantable defibrillator currently marketed by Eli Lilly's subsidiary CPI. However, Petitioner Eli Lilly would have this Court construe 35 U.S.C. § 271(e)(1) in a manner that will prevent Ventritex from clinically testing

¹ The Lilly '757 patent issued October 26, 1971 and normally would have expired on October 26, 1988. The patent term was extended to October 26, 1990 pursuant to 35 U.S.C. § 156. The first implantation of the Ventritex defibrillator occurred in July, 1989.

its implantable defibrillator until the extended period of Eli Lilly's patent has terminated.

Ventritex, Inc., a company that was formed for the purpose of developing a lifesaving medical device, is in a unique position to provide this Court with a realistic picture of how the proper interpretation of section 271(e), i.e., the Federal Circuit's construction of section 271(e)(1), stimulates innovation regarding improved medical devices. Ventritex is also in a strong position to demonstrate the fallacy inherent in Petitioner's argument that a medical device must be distinguished from a drug when construing section 271(e). Ventritex will demonstrate that no logical reason exists to distinguish between an improved medical device and an improved drug.

SUMMARY OF THE ARGUMENT

This case presents to this Court the construction of 35 U.S.C. § 271(e)(1), a statute which immunizes from patent infringement the making, using or selling of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (1988). The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, is clearly a law which regulates the manufacture, use, or sale of drugs and also clearly regulates the manufacture, use or sale of medical devices. Thus, the use of a patented invention for the development and submission of information concerning medical devices required by the FDCA is not an act of infringement.

Allowing a patent owner to prevent clinical trials of an improved medical device would discourage innovation. If this Court were to adopt Petitioner's statutory construction of section 271(e), the holder of a patent on a roughly-conceived²

² Roughly conceived insofar as there is no working prototype until ten years after the patent issues.

medical device could subject the invention to five years of clinical trials, obtain a five-year extension to the original seventeen-year patent, and then prevent competitors from clinically testing an improvement until the end of the extended term, some twenty-two years from the issue date of the patent. Clinical trials of improved, lifesaving devices by would-be competitors might take five more years, effectively rendering the next generation of medical devices commercially unavailable to the public for twenty-seven years after the issuance of the original patent.³

The fast developing world of medical technology requires investment in new companies that are willing to innovate. However, a new company founded on improving a patented medical device would find it very difficult to function if it could not clinically test its improved medical device until after the extended term of the dominant patent had expired. This would significantly discourage innovation as investment would be stifled.

Petitioner's contention that section 271(e)(1) was enacted to immunize the testing of generic drugs bypasses the fact, not disputed by Petitioner, that the statute also immunizes the testing of improved drugs which are *not* generic or bioequivalent. Improved drugs, which are still covered by patent, may have properties that are far superior to the patented drug that is being marketed by the patent owner. Clinical trials of the improved drug, which may take sales away from the patented drug, are required by the FDA and are indisputably immunized by section 271(e)(1). Likewise, improved medical devices, which are covered by a dominant medical device patent but which may have far superior capabilities, are contended by Petitioner as not being immunized from infringement by section 271(e)(1). As a matter

³ The rapid advances in medical technology continually decrease the period of time between each successive generation of new devices.

of public policy and simple logic, there is no rational reason for Congress to have immunized the testing of improved drugs under section 271(e)(1) while permitting the patent owner to prevent clinical trials of improved medical devices. Petitioner's argument is particularly disingenuous in view of the congressional grant of extended patent terms for improved drug and medical devices based on the clinical trials required for both. 35 U.S.C. § 156 (1984).

ARGUMENT

I. Exempting The Clinical Testing Of Improved Medical Devices From Patent Infringement Under Section 271(e)(1) Is In The Public Interest.

A. The Public Interest Is Served By Placing Improved Medical Devices Before The Public.

Providing the public with an improved lifesaving medical device is obviously in the best interest of society. The superiority of Ventritex's defibrillator over the Lilly CPI defibrillator is readily apparent. Lilly's defibrillator does nothing more than provide a high energy shock to deliver a rapidly beating heart back to normal sinus rhythm.⁴ In contrast, Ventritex's defibrillator also treats tachycardia and bradycardia with pacemaker therapy having a much lower energy level. Pacemaker therapy provides little or no discomfort to the patient, in contrast to the pain concomitant with the much higher energy shocks from Lilly's defibrillator.

For patients who need pacing as well as defibrillation, Lilly requires that two separate units, with separate leads, be implanted. Worse yet, the implanted units may interfere with the operation of each other (JA51, 75).⁵ On the other

⁴ Abnormal heart rhythm, or arrhythmia, includes fibrillation (fluttering of the heart), tachycardia (abnormally fast heartbeat), and bradycardia (abnormally slow heartbeat).

⁵ "JA" refers to the designated pages of the Joint Appendix filed with Petitioner's Brief.

hand, the implantable defibrillators manufactured by Ventritex are superior in that they combine (1) a pacemaker to detect and treat bradycardia and tachycardia and (2) a defibrillator, in a single unit. The pacemaker and defibrillator functions are effectively integrated to support each other.

Lilly plainly seeks to have this Court construe section 271(e)(1) so that companies such as Ventritex cannot even clinically test these superior devices during the extended period of Lilly's patent in order to provide these lifesaving devices to the public as soon as possible after Lilly's patent expires. Lilly's construction would divert the resources of a new company into defending an expensive lawsuit instead of enabling the company to direct its resources into obtaining FDA approval of its improved medical device.

Beyond the overriding public interest in getting lifesaving devices before the public, the sooner the improved medical device can be commercialized, the sooner investors will see a return on their investment making them more likely to invest in a new company such as Ventritex. Investment in start-up companies which intend to develop improved medical devices is significant to the economic and physical health of this country, benefiting not only the investors but also the public at large. There is a need to foster the revival of the entrepreneurial spirit in order to compete in this global economy. Investments in new companies, which have the personnel and desire to develop and produce an improved device, must be encouraged.

B. FDA Control Of Medical Device Clinicals And Section 271(e) Work In Harmony To Protect The Public Interest And Lilly.

Lilly complains that it would lose significant business during clinical testing of infringing improvements by others. The record proves otherwise (JA31, 106, 114). Clinical testing is strictly regulated by the FDA (21 C.F.R., Part 812;

JA143-53). Careful and detailed records must be maintained (21 C.F.R. § 812.140). There can be no commercialization of the device during clinical testing (21 C.F.R. § 812.7). The number of implantable devices and the number of investigators is limited (21 C.F.R. § 812.25, § 812.43). The number of patients whom the investigators can treat is limited (21 C.F.R. § 812.25). The device cannot be commercialized by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling (21 C.F.R. § 812.7(b)). The clinical testing cannot be unduly prolonged (21 C.F.R. § 812.7(c)). Thus, the manufacturer would not be able to extend its clinical testing of the device over an extraordinary period of time in order to avoid infringement.

The language of section 271(e) immunizes the manufacturer from infringement only if the patented invention is made, used or sold "solely for uses reasonably related to the development and submission of . . . [I.D.E.] information." If a manufacturer were abusing the clinical trial immunity, the manufacturer's acts would not be "solely for uses reasonably related to the development and submission of . . . [I.D.E.] information." See, e.g., *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 666 F. Supp. 1379, 1395-97 (N.D. Cal. 1987), *modified on other grounds*, 678 F. Supp. 1429 (N.D. Cal. 1988), *summary judgment granted*, 707 F. Supp. 1547 (N.D. Cal. 1989); *American Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86 (D. Del. 1989).

It has been suggested on page 31, n.21 of Petitioner's brief that clinical trials in the United States may be unnecessary because the start-up company could perform clinical trials of the device overseas to avoid infringement. This suggestion is meritless and impractical with respect to a start-up company. First, in order to avoid infringement if 271(e)(1) did not cover devices, a company would also have to *manufacture* the device overseas. Second, in order to manufacture overseas,

a company would require an overseas factory, equipment, training of foreign personnel, and components which must be made overseas. The company would need facilities which duplicate its United States facilities, requiring extraordinary expense. Since it is difficult enough for a start-up company to survive, the additional expense required to support an overseas manufacturing operation would be devastating. The benefits to this country of having the production facilities located here, where United States workers are employed and where the components are purchased, are obvious.

II. The Public Interest Is Not Served By Lilly's Construction Of Section 271(e)(1).

It would be contrary to public policy for the statute to be construed to provide an infringement exception for the clinical trials of pharmaceutical drugs but not for the clinical trials of medical devices. Medical devices are constantly being improved. Lilly obtained the significant advantage of two years of patent term restoration (35 U.S.C. § 156) for the clinical testing of its defibrillator. Now Lilly maintains that its potential competitors cannot clinically test their defibrillators until Lilly's patent term extension expires. The specific facts of the instant case show the inequity and illogical nature of Lilly's contention.

Lilly's predecessor-in-interest filed the patent application on the implantable defibrillator in 1967. At that time, the defibrillator was merely a concept—there was no useful operable device. The patent issued in 1971. It was not until 1980 that the first human implant occurred and not until 1985 that the FDA approved the defibrillator for commercial use. During the time period from the patent's issuance in 1970 and the approval for commercialization in 1985, Lilly's predecessor-in-interest had full patent rights. The patent rights include the right to prevent others from making, using or selling the invention. However, others could have, and did, develop a superior device. Although Lilly's patent would

normally have expired in 1988, as a result of the Patent Term Restoration Act, 35 U.S.C. § 156, Lilly was able to obtain a two-year patent extension. The patent will not terminate until 1990. During the 1971-1990 patent term, there was much time for other companies to develop improved implantable defibrillators. Yet, these improved defibrillators cannot be commercialized because they have not been approved by the FDA.

Clinical testing of Ventritex's defibrillator began in July of 1989, during the extended period of the Lilly patent. There is no possibility that the clinical trials will be concluded and that its device will receive FDA approval prior to the expiration of the Lilly patent. However, Lilly urges this Court to construe section 271(e)(1) so that the clinical trials, which are required for FDA approval and eventual commercialization of the device, constitute patent infringement. Notwithstanding the two-year extension obtained by Lilly, Lilly expects all potential competitors to wait until Lilly's patent has expired before commencing clinical trials, thereby giving Lilly an effective patent term for preventing commercialization by others that is substantially greater than the nineteen-year term that it was granted. Thus, Lilly seeks to benefit from an additional extension to the section 156 extension that it has already received. This is contrary to what Congress intended in passing section 271(e)(1).

III. No Logical Differentiation Exists Between Improved Medical Devices And Improved Drugs.

No logical reason permits differentiation between an improved medical device and an improved drug. Indeed Lilly cannot deny that section 271(e)(1) immunizes clinical testing of an improved drug from patent infringement.⁶ On pages 28-30 of its brief, Petitioner contends that there are

⁶ Lilly concedes that section 271(e)(1) "also permit[s] clinical trials of patented drugs...". Pet. Brief at page 30 n.2.

important distinctions between FDA regulation of drugs and medical devices. These apparent distinctions, however, only apply to generic drugs. They do not apply to improved drugs. An improved drug is one that is covered by a dominant patent, but is not marketed by the patentee. The improved drug has properties that are different enough from the patent owner's FDA-approved drug that it is not bioequivalent and, thus, requires full clinical testing.

For example, assume that pharmaceutical company 1 obtains a patent on an anticoagulant drug having a composition of elements A, B and C, and company 1 successfully markets the drug after clinical trials and FDA approval. Then competitor 2 develops an anticoagulant drug which is greatly superior to company 1's drug, but company 2's drug contains a composition of elements A, B, C and D. Company 2's drug is not bioequivalent to company 1's drug and full clinical trials are required for FDA approval. Company 2 would be able to engage in such clinical trials because it is excused from patent infringement under section 271(e), even though company 1's patent covers company 2's improved drug.

Now assume that company 1 owns a patent on a medical device for treating cardiac patients, with the device comprising a combination of elements E, F and G. During the patent term, company 3 develops a greatly superior medical device, comprising elements E, F, G, H and I. Since the superior medical device is not identical to the medical device being marketed by company 1 that is FDA approved, company 3's medical device will have to be clinically tested for FDA approval. There is absolutely no reason why company 2's drug should be immune from patent infringement while company 3's medical device should not be immune from patent infringement. Contrary to Lilly's contention on page 30 of its brief, the "abbreviated procedure for pre-market approval" does not apply to either the improved drug or to the improved medical device, yet the improved drug is

indisputably immune from patent infringement during clinical trials. Thus, Lilly's argument concerning limited bio-equivalence testing is totally inapplicable to improved drugs, which fall within the section 271(e)(1) exception.

Further, just as the clinical testing of the medical devices may render certain patients unavailable as customers to the patent owner, the clinical testing of the improved drug may also render patients using that drug during clinical trials to be unavailable as customers to the patent owner. Lilly's contention, on page 31 of its brief, that the clinical trials could "rob patent holders" in lost sales is frivolous in view of the added years to the patent resulting from 35 U.S.C. § 156. A competitor could just as easily state that the extended period of time that Congress has allowed to be added to drug and medical device patents "robs" competitors in lost sales of improved drugs and improved medical devices.

CONCLUSION

For the foregoing reasons *amicus* Ventritex submits that the judgment of the Court of Appeals for the Federal Circuit should be affirmed.

Respectfully submitted,

GEORGE H. GERSTMAN
GERSTMAN & ELLIS, LTD.
Two North LaSalle Street
Suite 2010
Chicago, Illinois 60602
(312) 263-4350
Attorney for *Amicus*
Ventritex, Inc.

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

BRIEF OF
PARALYZED VETERANS OF AMERICA
AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

CHARLES L. GHOZ
JEFFREY H. KAUFMAN
Counsel of Record
OBLON, SPIVAK, McCELLAND,
MAIER & NEUSTADT, P.C.
Fourth Floor
1755 Jefferson Davis Highway
Arlington, Virginia 22202
(703) 521-5940

*Attorneys for Amicus Curiae
Paralyzed Veterans of America*

Of Counsel:
ROBERT L. NELSON
General Counsel
Paralyzed Veterans of America
801 18th Street, N.W.
Washington, D.C. 20006
(202) USA-1300

BEST AVAILABLE COPY

QUESTION PRESENTED

Whether the Federal Circuit erred as a matter of law in interpreting the ambiguous language of 35 USC 271(e)(1) to include medical devices regulated by the Food and Drug Administration ("FDA") as well as drugs regulated by the FDA.

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MEDTRONIC, INC.,

Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

BRIEF OF
PARALYZED VETERANS OF AMERICA
AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

Paralyzed Veterans of America submits this brief amicus curiae in support of respondent Medtronic, Inc. It is accompanied by written consents from the petitioner and the respondent.

INTEREST OF AMICUS CURIAE

Paralyzed Veterans of America ("PVA") is a non-profit organization chartered by the Congress of the United States and dedicated to serving the needs of its members—all of whom have catastrophic paralysis caused by spinal cord injuries or diseases. The Medical

and Research Affairs Department ("MARAD") of PVA funds and oversees critical spinal cord injury research—research which is critical, not only to PVA's members, but to all those with paralysis. In particular, primary funding for the Center for Neuroscience and Regeneration Research at Yale University is provided by PVA and its chapters through MARAD.

The interest of PVA in this case is to insure that vital research pertaining to the development of medical devices is not impeded by patent disputes. PVA realizes, of course, that once the research has progressed to the point of introduction of a commercial medical device, the research institution or the sponsor of the research will have to pay tribute to valid patents just the way that it will have to pay for the raw materials it uses to build the medical devices. Before the research reaches that point, however, the patent law should not be available to stifle incipient competition.

ARGUMENT

Medical research tends to be (1) expensive and (2) risky—in the sense that most medical research turns out to have been unproductive.¹ Moreover, as correctly noted by amicus Neuromedical Technologies, Inc., many developers of medical devices are small companies, and many of those small companies are

¹ There is, of course, a value to learning how *not* to accomplish a desired goal. However, that information is not, generally speaking, something that can be sold, thereby recouping the investment in the research that generated that information.

devoted to commercializing a single product.² During the time that such companies are engaged in their vital research work, they are uniquely susceptible to the in terrorem effect of the patent law. Since, by definition, they do not yet have a commercial product, they normally have insufficient funds to litigate patent disputes (which are notoriously expensive). Moreover, since their products have not yet been developed to the point where they have received FDA approval (and may never be developed to that point), they have little incentive to invest what funds they do have in patent litigation rather than in medical research. Thus, it is distressingly easy for a well-funded company to stifle incipient competition before the incipient competitor has gotten to the point that it can, or will wish to, fight back.

As correctly found by the Federal Circuit, "the language [of 35 USC 271(e)(1)] is fraught with ambiguity."³ One can read it over and over again, each time convincing one's self that it means the opposite of what one convinced one's self that it meant the time before. Moreover, the legislative history is not really helpful—Congress simply didn't focus on this issue. (If it had, it might have written 35 USC 271(e) a little more clearly!)

Under the circumstances, PVA respectfully submits that what the Federal Circuit did (and what this court

² Brief of amicus Neuromedical Technologies, Inc. at pages 6-7. That amicus supports the petitioner, not the respondent, and it draws a different inference from this premise than does amicus PVA.

³ *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405, 10 USPQ2d 1304, 1306 (Fed. Cir. 1989).

should do) is to read the statute so that it achieves the best result for the patent system.⁴ As Chief Judge Markey of the Federal Circuit wrote of another ambiguous section of the patent statute in *Paulik v. Riskalla*, 760 F.2d 170, 226 USPQ 224 (Fed. Cir. 1985) (in banc):

A literal reading of § 102(g) is not here involved. That statute says not a word on whether suppression or concealment can or cannot be cured before the filing date of another. The court is therefore presented with a choice. Operating in the interstices of the statute, the court may read § 102(g) as permitting or forbidding such curing. Given that choice, it would seem imperative that the court choose the rule least disruptive of the daily workings of the patent system.⁵

This case could go either way as a matter of abstract logic. However, much more than abstract logic is at issue. To a significant extent, the future of re-

⁴ In this connection, it should be noted that the Federal Circuit is the court of patent appeals and that its members are presumed to have a special knowledge of patent law and a special sensitivity to the needs of the patent system.

⁵ 760 F.2d at 1283, 226 USPQ at 233 (additional views of Chief Judge Markey). See also *A.F. Stoddard & Co. v. Dann*, 564 F.2d 556, 566, 195 USPQ 97, 105 (D.C. Cir. 1988) ("Courts of the Judicial Branch . . . , having the obligation to administer justice, may on rare occasions be required to delve within the interstices of a statute to do justice, not only to the individual or individuals involved, but to the statutory scheme itself.") *Stoddard* involved a longstanding ambiguity in 35 USC 116—an ambiguity which Congress later remedied by amending the statute to correspond to the court's opinion in *Stoddard*. P.L. 97-247, Sec. 6(a), 96 Stat. 320 (August 27, 1982).

search in medical devices by small companies in the United States is at issue. The Federal Circuit reached a result that favored such research—somewhat at the expense of the larger and better financed competitors of those small companies. Congress could change that result if it wants to by rewriting and clarifying 35 USC 271(e)(1). However, it is respectfully submitted that this court of generalists should not substitute its judgment for the judgment of the court of specialists below in what, at base, is a judgment call on a highly debatable point.

Respectfully submitted,

CHARLES L. GHOLZ
JEFFREY H. KAUFMAN
Counsel of Record
OBLON, SPIVAK, MCCLELLAND,
MAIER & NEUSTADT, P.C.
Fourth Floor
1755 Jefferson Davis Highway
Arlington, Virginia 22202
(703) 521-5940

*Attorneys for Amicus Curiae
Paralyzed Veterans of America*

Of Counsel:
ROBERT L. NELSON
General Counsel
Paralyzed Veterans of America
801 18th Street, N.W.
Washington, D.C. 20006
(202) USA-1300

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**BRIEF OF AMICI CURIAE
UNIVERSITY OF MINNESOTA AND
TULANE UNIVERSITY IN SUPPORT OF
RESPONDENT MEDTRONIC, INC.**

William P. Donohue
Counsel of Record
UNIVERSITY OF MINNESOTA
330 Morrill
100 Church Street S.E.
Minneapolis, MN 55455
(612) 624-4100

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RESPONDENT MEDTRONIC, INC.**

INTEREST OF THE AMICI CURIAE

The University of Minnesota and Tulane University (the "Academic Research Centers") jointly submit this brief amici curiae in support of Respondent Medtronic, Inc. on the writ of *certiorari* to the United States Court of Appeals for the Federal Circuit.

The Academic Research Centers are institutions of higher learning that are concerned about preserving a broad experimental use exemption to patent infringement to foster research and the expansion of knowledge, and who support in particular the exemption from infringement extended to FDA testing of medical products by section 271(e)(1) as construed by the Federal Circuit. The Academic Research Centers are engaged in extensive research in the medical field (as well as in other fields), and the decision of this Court could define the boundaries of the freedom to conduct that research. We are participating in this matter to urge the Court to consider the interest of U.S. Academic Research Centers in conducting all forms of research without being subject to limitations that interfere with the advancement of science and knowledge in this country.¹

The Academic Research Centers conduct research that is both publicly and privately sponsored. In many instances, private sponsors fund research on products that they intend to market. Income from sponsors of that research, and later from licenses with commercial entities, represents a significant and increasing source of funding for teaching and research institutions in the United States. If the Federal Circuit decision is reversed, that source of funding for improvements in medical device technology could be threatened.

It has been suggested by petitioner and its supporters that research can be conducted outside of the United States. It is, however, both unfair and shortsighted to suggest that this could be done without causing a shift

1. Tulane University has no clinical, financial, or service affiliation with Medtronic. Medtronic does, however, maintain a cardiovascular research program at the University of Minnesota Medical School, and has endowed a chair at the recently established biomedical engineering center. The medical school is an approved clinical investigation center for the Medtronic Model 7216A PCD device and separately contracts from time to time to conduct clinical research on other medical devices.

of both expertise and funding to foreign markets. Corporate sponsorship would dry up. The U.S. medical products field, in particular, would suffer as the result of work and innovation performed beyond its borders.

The Academic Research Centers have a common interest shared by other similarly oriented institutions in preserving the freedom to do research, fostering advances in science and technology, and educating America's future scientists, engineers, and physicians. Those interests are congruent with the public interest of promoting the progress of science and the useful arts. This Court is requested both to affirm the Federal Circuit decision on *certiorari* to allow for FDA testing of medical devices prior to patent expiration and to reassert the traditional experimental use exception consistent with the policies behind the Constitution.

SUMMARY OF THE ARGUMENT

Pursuant to the power given by Article I, Section 8, clause 8 of the U.S. Constitution "To Promote the Progress . . . Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries," Congress has provided that a patentee may exclude others from making, using, or selling the patented invention in the United States during the term of the patent. 35 U.S.C. § 154. However, Congress has given no definitions of these prohibited activities, leaving that task to the courts.

Further, while promotion of scientific and technical progress is accomplished by inducing inventors to disclose, and ultimately to dedicate to the public, beneficial advances in knowledge and technology by awarding them a limited period in which they can profit from their invention to the exclusion of others, the reward of the individual is secondary to the public benefit. It would not be in the public interest to prevent basic research in the field of a patent for up to twenty-two years as is being

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**BRIEF OF DR. DENTON COOLEY AS AMICUS
CURIAE IN SUPPORT OF RESPONDENT**

MARGARET E. ANDERSON
Counsel of Record

BROWNING, BUSHMAN,
ANDERSON & BROOKHART
5718 Westheimer
Suite 1800
Houston, Texas 77057
(713) 266-5593

Counsel for Amicus

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**BRIEF OF DR. DENTON COOLEY AS AMICUS
CURIAE IN SUPPORT OF RESPONDENT**

INTEREST OF THE AMICUS CURIAE

Dr. Denton Cooley submits this brief amicus curiae in support of respondent MEDTRONIC, INC. on the writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered March 29, 1989.

Dr. Denton Cooley, M.D. is an internationally renowned cardiac surgeon. He is also the Surgeon in Chief of the Texas Heart Institute, one of the world's leading cardiac research centers, located in Houston.

Dr. Cooley, together with his colleagues at the Texas Heart Institute, is actively involved in research into the causes and treatment of cardiac disease. This research includes carrying out clinical trials of new drugs and medical devices developed by pharmaceutical companies and medical device manufacturers.

Dr. Cooley also has an extensive practice treating patients, many of whom have advanced or complicated conditions which are not readily treatable by conventional means. It is very important to him to be able to offer all his patients the best available treatment for their particular condition.

In addition, Dr. Cooley's position at the Institute involves him in raising funds for the research activities. As federal spending has been cut back in recent years, the money for research has increasingly had to come from industry.

All these activities would be adversely affected if the very narrow view of the scope of 35 U.S.C. § 271(e)(1) put forward by petitioner Lilly and its supporting amici were to prevail. Clinical trials of new devices would be fraught with the danger of patent infringement litigation, and even animal and bench testing would be affected by this chilling threat. A likely result is that much clinical research involving medical devices will be driven out of the United States to foreign research institutes in countries where the law is not so restrictive, closely followed by the best physicians and surgeons and the corporate research

support. The Texas Heart Institute could not maintain its present world leadership role in cardiac research and treatment under those circumstances.

SUMMARY OF ARGUMENT

Congress cannot have intended the 1984 provisions allowing testing for regulatory purposes prior to the expiry of a dominant patent to exclude medical devices, because the effects of excluding medical devices are clearly contrary to the public interest.

The inability to perform clinical testing until the dominant patent has expired, which could be longer than the basic seventeen years if an extension is obtained, could seriously delay the introduction of improved technology. It may even result in some improvements not being made at all. This could have a serious effect on the standards of patient care in this country.

If the testing were to be done abroad, as Lilly wants, the final result will be that the United States will lose some of its most innovative doctors, medical scientists and engineers, and much-needed corporate funding, to foreign institutions. Such a loss of talent and funds can only damage this country's standing as a leader in the development of medical technology.

ARGUMENT

Petitioner Lilly is contending for an interpretation of 35 U.S.C. § 271(e)(1) which would outlaw all U.S. clinical testing of new medical devices which come within the claims of an existing patent for the whole term of the patent, including any extension. This interpretation, combined with the present law which does not exempt from

infringement experimental use where there is an ultimate commercial motive, however remote, behind the experiments, would have a disastrous effect on research into and treatment of cardiac disease in the United States. This would be contrary to the constitutional intent behind the patent system of promoting the progress of science and technology, and thus is not likely to have been the intent of Congress in enacting section 271(e)(1).

I.

Clinical Trials Of Medical Devices Are Vitally Important In The Treatment Of Heart Disease

It is the literal truth to call medical devices such as implantable defibrillators "life-saving". There are many patients who today are leading healthy, enjoyable lives, who just a few years ago would have been unable to live a normal life, or who may even have died. This is thanks to the remarkable advances in medical device technology that have occurred in recent years.

These rapid advances in medical technology will continue, given the right climate for research and testing. This will require sufficient funding, innovative engineers and doctors, the ability to do bench and animal testing of prototype devices, and the ability to do scientific clinical trials on human subjects. Up until now, all of these ingredients have been present in the United States, making this a leading country in medical device development.

A total inability to perform clinical trials until the expiry of the seventeen year patent term (or even longer, if Lilly's claim to benefit from the patent term extension without the *quid pro quo* of pre-expiry regulatory testing

were to succeed) would seriously damage the whole program. Most cardiac medical devices become obsolete in a much shorter time than seventeen years, being replaced by improved, more sophisticated and reliable devices. Some of these improved devices can treat conditions that were previously untreatable, or can treat other conditions more effectively. If the lengthy testing needed to satisfy FDA requirements for new medical devices cannot begin in the United States until the expiry of the seventeen or more years of the patent term, at least some new devices may never be made.

II.

Lack Of Improvements Will Adversely Affect Patient Care

Doctors want to provide their patients with the best treatment available to deal with that person's particular condition. While a particular patented device will likely be of benefit to certain patients, it is unlikely to meet every need. An improvement to the patented device may be desirable to treat some conditions, but the patentee is not always ready or willing to make that improvement in the absence of competition. Some patients may be benefitted by being subjects in a clinical trial of an improved device, and it is to the advantage of the medical profession and their patients to have the improved device approved by the FDA as soon as possible.

On the other hand, where a tried and approved device meets the patient's needs, that device would normally be prescribed, not the experimental improvement. Lilly and certain of its supporting amici argue that there would be an enormous loss of sales as the result of clinical testing.

However, this ignores the fact that the majority of doctors, a body many times larger than the very limited number of doctors participating in the clinical trials, will be unable to prescribe the experimental device. Even those doctors in the trial are unlikely to select patients for the trial who can be treated perfectly well with the approved device. The loss of sales to the patentee as a result of clinical trials has been greatly exaggerated.

III.

Clinical Research In The United States Will Be Harmed

Lilly has several times suggested that there is no justification for allowing regulatory testing of medical devices prior to the expiration of the patent term, because such testing could equally well be done abroad. *See, e.g.*, Brief for the Petitioner, filed November 21, 1989, page 31 n.21, and Lilly's Application To Stay Mandate Of The Federal Circuit, filed in this Court, July 21, 1989, pages 21, 24-25. That is likely to have much more devastating effects on American medical research and device technology than allowing the regulatory testing of new devices prior to the expiration of a patent.

First, leading clinical researchers would want to go to where the testing is carried out. The innovators and leaders amongst medical practitioners would also want to be where they could participate in clinical trials and offer their patients the latest in medical technology. In fields like cardiology, patients will often travel across the world in order to receive treatment from well-known doctors at leading centers, such as the Texas Heart Institute. Of course, those Americans who could not afford to travel abroad would not be able to benefit from these advances being tested overseas.

It is possible that this loss of clinical research facilities would tend to draw the more basic research abroad as well. Certainly, corporations would be more likely to put research funds into organizations which could carry out clinical testing of new medical devices, so U.S. institutions could see a diminution in the funds available from industry for medical device research.

There is no doubt that even a partial shift to overseas institutions of research, of highly qualified doctors and researchers, and of research funding would seriously damage the United States' claim to be a leader in medical technology, as well as damaging the medical institutions in this country at which the research is carried on. It is unbelievable that this could have been the intention of Congress.

Respectfully submitted,

MARGARET E. ANDERSON
Counsel of Record
BROWNING, BUSHMAN,
ANDERSON & BROOKHART
5718 Westheimer
Suite 1800
Houston, Texas 77057
(713) 266-5593

Counsel for Amicus

Dated: December 30, 1989

In considering the Drug Price Competition and Patent Term Restoration Act of 1984, Congress made it clear that except for the limited patent term extension for which it was providing, there was to "be no other direct or indirect method of extending patent term." H.R. Rep. 98-857, 98th Cong., 2d Sess., pt. I, at 15 (1984). There is no dispute about that. The idea was to make the patent owner "whole", to give him back as much of his original 17-year commercial term as possible. No one ever contemplated giving him a *bonus*.

What does Lilly say about an original 17-year patent monopoly being transformed into an effective 19-year monopoly? Lilly has taken the position that the illustrated *de facto* extension of the original term can be avoided because the competitor may begin testing *outside the United States* during the 2-year patent term extension. (Lilly Brief, p. 31 n. 21). (Presumably, foreign testing could begin even earlier.) Lilly says that under 21 C.F.R. Section 814.15, the FDA can approve a medical device based solely on foreign testing. The real question, however, is whether Congress could possibly have intended, when drafting a Statute designed to balance competitive domestic interests, that all American medical device manufacturers (except the patent owner) should ship their manufacturing and clinical affairs departments overseas so that American pacemakers, insulin pumps, hearing prostheses, etc. could be tested only on non-Americans. According to Lilly, the answer has to be in the affirmative.

Lilly must also be proceeding on the assumption that the rest of the world lacks effective patent enforcement procedures which might otherwise block the conduct of a clinical trial in a foreign country in which Lilly has also secured patent protection.

Any interpretation of Section 271(e)(1) must take into account the possible extension of a patent under jointly-enacted Section 156. Lilly obtained the benefit of just such an extension; only by construing Section 271(e)(1) as applying to medical devices will impermissible *de facto* extensions be avoided.

CONCLUSION

For the foregoing reasons, Teletronics respectfully submits that this Court should affirm the Federal Circuit's decision.

Respectfully submitted,

MICHAEL I. RACKMAN
(Counsel of Record)
BARRY A. COOPER
GOTTLIEB, RACKMAN & REISMAN
1430 Broadway
New York, New York 10018
(212) 869-2890

Counsel for Amicus Curiae
Teletronics, Inc.

Of Counsel:

WILLIAM C. NEALON, Esq.
40 Crane Hill Road
Suffield, Connecticut 06078
(203) 668-0226

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IN SUPPORT OF THE RESPONDENT**

MICHAEL I. RACKMAN
(Counsel of Record)
BARRY A. COOPER
GOTTLIEB, RACKMAN & REISMAN
1430 Broadway
New York, New York 10018
(212) 869-2890

*Counsel for Amicus Curiae
Teletronics, Inc.*

Of Counsel:

WILLIAM C. NEALON
40 Crane Hill Road
Suffield, Connecticut 06078
(203) 668-0226

QUESTION PRESENTED

Does 35 U.S.C. Section 271(e)(1) apply to medical devices as well as to drugs and veterinary biological products?

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**BRIEF OF AMICUS CURIAE
TELECTRONICS, INC.
IN SUPPORT OF THE RESPONDENT**

INTEREST OF AMICUS

Telectronics, Inc. ("Telectronics") respectfully submits this brief as *amicus curiae* in support of the position of Respondent Medtronic, Inc. ("Medtronic"). Counsel for Petitioner Eli Lilly and Company ("Lilly") and for Medtronic have both consented in writing to the filing of this brief.

Telectronics has an interest in this proceeding since Telectronics is a plaintiff in a declaratory judgment action now pending before the United States District Court for the District of Colorado entitled "Telectronics, Inc. v. Eli Lilly & Company, Inc. and Cardiac Pacemakers, Inc.", Civil Action No. 88-M-1815. Telectronics has asserted in that action that it has not infringed U.S. Patent No. Re. 27,757 ("the '757 patent"),

the same patent which has been asserted by Lilly in the litigation with Medtronic now before this Court. Lilly has alleged, by way of counterclaim in the Colorado action, that a medical device developed by Teletronics infringes the '757 patent, despite the fact that this device is still in a non-commercial clinical testing program directed to obtaining the required premarket approval from the Food and Drug Administration.

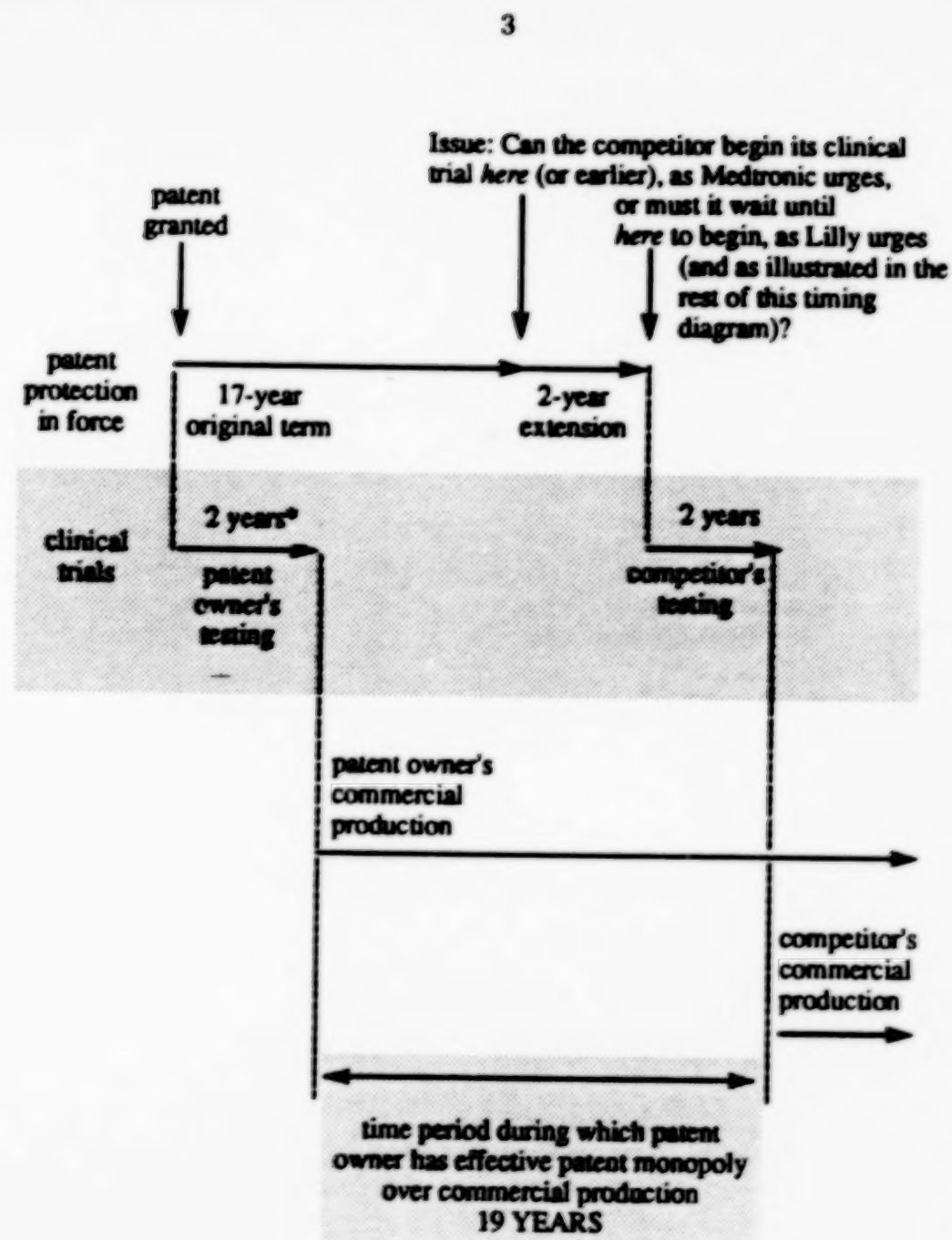
Teletronics therefore has an interest in the decision of this Court on the issue of whether or not the Section 271(e)(1) exemption for FDA testing is applicable to medical devices.

SUMMARY OF ARGUMENT

Lilly obtained an extension, under 35 U.S.C. Section 156, extending the "life" of its patent monopoly for two years. Section 271(e)(1) must be read in conjunction with the extension provisions of 35 U.S.C. Section 156. Congress made it clear that there were to be no other *de facto* extensions of the patent monopoly. Only by construing Section 271(e)(1) to encompass medical devices will Congress' intent be realized.

ARGUMENT

A picture is worth a thousand words. The '757 patent would normally have expired in October, 1988, but Lilly obtained a two-year extension of the patent, pursuant to 35 U.S.C. Section 156. If time is measured from left to right, the following sketch depicts the issue before the Court and, because it is based on Lilly's view, it shows that the patent owner's effective monopoly (during which it is the only party capable of commercial production) is 19 years:



* The patent owner's testing can begin even before the patent issues. If it does, the effective patent monopoly is even longer.

sought by petitioner here, nor to prevent improvements being made by others upon the patented invention during that time.

The need to allow certain uses of the patented invention in order to carry out the Constitutional policy was recognized very early on by the courts in the so-called "experimental use exception" to infringement. As originally enunciated by Justice Story in 1813, this exception provided a careful balance between the public interest and the reward given to the inventor. Unfortunately, more recent decisions have narrowed the exception. In particular, the benefit of the exception has effectively been denied to any actual or potential competitor, the only people who are likely to have the funds or incentive to develop improvements. The balance has been shifted away from the advancement of knowledge for the public benefit, and towards the interests of the individual patentee.

Congress, in enacting 35 U.S.C. § 271(e)(1), recognized in part the need to stimulate public innovation and research, and established an exception to infringement for FDA testing. The plain meaning of that statute, and its legislative history, establishes that it extends to the FDA testing of all medical products, devices as well as drugs. However, the statute fails to specifically deal with, in a positive or negative sense, the broader scope of the traditional experimental use exception. Further, petitioner and its amici would now have that section substantially limited by judicial legislation to exclude from its infringement exemption all medical products but drugs. This would clearly not be in the public interest.

ARGUMENT

Amici Academic Research Centers respectfully request the Court to maintain the balance in its proper place, and confirm an experimental use exception that

permits research for the accumulation of knowledge and scientific data and allows competitive testing, both FDA-related or otherwise, regardless of whether there is an ultimate commercial motivation behind these activities.

Petitioner Lilly and its supporting amici are requesting that the Court substantially expand the rights of medical device patentees, enabling a patentee to prevent others from beginning even FDA-regulated testing for new devices until after patent expiration. The direct result of such an alteration in the law would be to grant medical device patentees a significant *de facto* extension, above and beyond any statutory extension, effectively preventing the availability of new technology until the completion of that testing several years after patent expiration. Such a judicially legislated expansion could affect timely, leading-edge research and development on medical devices in the United States, particularly in the university arena. This was not the intent of Congress when it enacted 35 U.S.C. § 271(e)(1), nor is it in keeping with the original constitutional intent behind the present U.S. patent system.

I. THE PATENT SYSTEM WAS INTENDED TO INCREASE THE STORE OF PUBLIC KNOWLEDGE AND TO STIMULATE DOMESTIC INNOVATION

A patent gives its owner "... the right to exclude others from making, using, or selling the invention throughout the United States. ..." for a term of seventeen years. 35 U.S.C. § 154. These or similar words have appeared in every United States patent statute since the original Patent Act of 1793. Congress has never provided a statutory definition of these terms, leaving their scope to judicial interpretation. *Roche Prods., Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 496 U.S. 856 (1984).

On its face, the language used by Congress forbids all uses of the patented invention. However, the early

courts recognized that prohibiting certain uses could be contrary to the policy underlying the patent system.

[I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable source of interpreting the meaning of any writing; be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Cabell v. Markham, 148 F.2d 737, 739 (2d. Cir.) (Judge Learned Hand), *aff'd*, 326 U.S. 404 (1945). The term "use" in the patent statutes has never been extended to every possible use. *Roche*, 733 F.2d at 861. Examination of the Constitutional principles of the patent system shows that an effective exception for research is vitally necessary to the public interest.

This Court has long recognized the principles underlying the United States patent system: "This court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and the useful arts.' (Constitution, Art. I, § 8)." *Motion Picture Patents Co. v. Universal Film Mfg.*, 243 U.S. 502, 512 (1917).²

In its most recent decision on patent matters, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, ___ U.S. ___, ___, 109 S. Ct. 971, 975 (1989), Justice O'Connor, writing for the unanimous Court, stated:

2. See, also, *Shaw v. Cooper*, 32 U.S. 292, 314-16 (1833); *U.S. v. Masonite Corp.*, 316 U.S. 265, 280 (1942); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964); *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 530-31 (1972).

The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and the Useful Arts." . . .

* * *

From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.

It is clear that the patent statutes must be interpreted so that the interest of the patentee is not overly protected to the public detriment.³

The primary means of furthering the constitutional purpose of promoting the progress of science and useful arts is by encouraging disclosure of information that adds to the public store of available knowledge.

When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

3. This principle is at the root of the Anglo-American patent jurisprudence. The English Statute of Monopolies, 1623, 21 Jac., c.3, § 14, which exempted letters patent from the general prohibition of monopolies, also contained the limitation that letters patent were not to be granted if they would be contrary to the law, "mischievous to the State, by raising prices of Commodities at Home or Hurt of Trade, or generally inconvenient."

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974). However, if this information cannot be used by the public even for research purposes, then very little benefit would be obtained in return for that extensive period of exclusivity, and that period would be effectively lengthened. It is, therefore, inconsistent with patent system policy to allow the patent owner to prevent all use of the information disclosed in the patent until the patent expires.⁴ This is particularly true of uses that do not appropriate any of the financial rewards of exclusivity.

The increase in public knowledge encouraged by the patent system is not for pure intellectual satisfaction. It is to stimulate the search for further knowledge and the development of improved technology. It is only through such research and development that progress in science and the useful arts is assured. This research and development in a free market economy is spurred on by the need to compete with the patentee.⁵ If the preliminary research and testing necessary to such competition were made impossible during the patent term, technological progress would slow to a snail's pace. This is not what the founding fathers intended.

4. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 219 (1987), comments that:

If the public had absolutely no right to make, use, or sell the patented invention until the end of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure at the *beginning* of the term. The requirement of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute patent infringement. (Emphasis in original.)

5. A practical description of the effect of a strong patent system in a competitive market in spurring improvements and new developments, given by the late Charles E. Lucke, professor and head of the Mechanical Engineering Department of the School of Engineering of Columbia University, can be found in 1 LIPSCOMB'S WALKER ON PATENTS, § 1:8, 55-56 (3rd ed. 1984).

II. PREVENTING TESTING PRIOR TO PATENT EXPIRATION WILL UNDERMINE RESEARCH EFFORTS ON MEDICAL DEVICES IN THE UNITED STATES

Teaching hospitals, in conjunction with their affiliated universities, serve a critical and indispensable role in domestic research and public health. For all practical purposes, university hospitals are the only places *in the United States* where clinical testing of new medical products can be conducted. Such necessary clinical testing should not be unreasonably stifled to the detriment of the public by judicially legislated expansion of patent rights. Yet, this is exactly what petitioner requests here. Petitioner and its amici claim, without any record support, that the decision below will significantly impede the availability of new medical products and discourage innovation in the medical product field. In fact, just the opposite is true. It is the adoption of petitioner's view that would chill medical device innovation.

As justification for its view, petitioner has repeatedly stated that Medtronic and other medical product developers are free to take their clinical testing overseas and, thereafter, to use the results of that testing to obtain U.S. FDA approval.⁶ It is just this unfortunate scenario that *will* occur, however, should the exemption of section 271(e)(1) be withdrawn from non-drug medical products, and it is precisely this scenario that should be prevented. Substantial harm to U.S. research and development efforts will result from adoption of petitioner's

6. Indeed, this was also one of Lilly's principal justifications in support of maintaining an injunction against Medtronic prohibiting testing in the United States. See, e.g., Lilly's Application To Stay Mandate Of The Federal Circuit, filed in this Court July 21, 1989, pp.21, and 24-25; and Lilly's Reapplication For An Order To Recall And Stay The Mandate, filed here October 20, 1989, pp.3, 6, and 9.

position, irretrievably stifling U.S. innovation in favor of foreign research and testing.

The harm results from the fact that in the university environment, and particularly in the medical products field, participating in the development of the latest technology is critical. Leading researchers are drawn to locations where they can work on cutting edge technologies. Petitioner would send those innovators overseas.

There is no disagreement that FDA experimentation involving drugs is exempt from infringement. But the drug field is more static than the medical device field. Once a particular drug is found to be effective in a particular application, there is little incentive to develop other drugs to accomplish the same result. Thus, the commercial lifespan of a drug can continue indefinitely. It is quite common for a once-patented drug (for example, aspirin) to remain in strong demand well after the expiration of the patent. Indeed, the very existence of the generic drug industry attests to that fact.

Medical device technology, on the other hand, is constantly changing, providing newer, more precise, and more reliable devices to supplant older ones. Once it is the law that these newer medical devices can be experimentally evaluated and clinically tested in foreign countries years earlier than in the United States, however, those who perform basic research on new products will naturally be drawn away from the United States and towards overseas testing facilities.

Although preliminary studies may remain possible at U.S. institutions, actual testing on animals and humans will not. However, these tests are key to ultimate advancement in the medical products field, because only animal and human testing can determine whether or not a particular device is safe and effective and only such tests can satisfy the FDA. The United States has the finest clinicians in the world. United States citizens deserve to have those clinicians evaluate new products at the earliest possible time.

Congress did not intend to stifle such early evaluation when it enacted section 271(e)(1).

Moreover, while university hospitals, as sites for clinical testing, presently employ many of the most innovative doctors and scientists, their work is enhanced by significant corporate sponsorship. Although the universities act as spawning grounds for significant new ideas, those ideas typically cannot be developed to the point of useful application to humans without the technical and economic resources, and practical knowledge, maintained within the commercial community. But again, if overseas testing of medical products is given a multi-year lead time, the realities of the marketplace will force corporate sponsorship to shift away from U.S. universities and towards support of foreign universities and facilities. In order to effectively enter a post-patent market, U.S. (as well as foreign) manufacturers will be compelled to spend their research dollars abroad. Once U.S. manufacturers have committed their efforts overseas, moving people and developing laboratories, there is a serious likelihood that those operations will not be returned, even after the relevant U.S. patents expire.

This is also not what Congress intended when it enacted section 271(e)(1).

The disclosure provisions of the patent laws are of little benefit in promoting U.S. scientific progress if the patents themselves, because of regulatory delays, preclude the entry of competing technology far beyond their expiration dates. The United States cannot afford to lose its lead in the medical device field simply because certain patentees desire to expand their patent rights beyond the bounds of the law and the intentions of Congress.

III. A BROAD INTERPRETATION OF SECTION 271(e)(1) IS IN KEEPING WITH THE TRADITIONAL EXPERIMENTAL USE EXCEPTION TO INFRINGEMENT

Experimental use of patented technology for the development and evaluation of improved medical devices should not be infringement even under the traditional experimental use doctrine. To limit that doctrine to only those experiments done for non-commercial purposes is to ignore the reality of modern university research. Even testing done for purely scientific purposes may be commercially motivated, and the data may represent an asset to the corporate sponsor of the research, but such testing must be recognized for its primarily experimental purpose and should not be precluded by a patent. Modern university research is no less beneficial to the public simply because it has an ultimate commercial objective or a corporate affiliation.

A. The History Of The Experimental Use Exception

The origin of an experimental use exception to the patentee's exclusive rights can be traced back to *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). Supreme Court Justice Story, sitting as a Circuit Judge, was deciding a motion for a new trial in a patent case based on objections to a number of directions given to the jury. One of the directions objected to was that "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right. . . ." Justice Story said of the direction:

[I]t was adopted by the court from the consideration that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Id., 29 F. Cas. at 1121. (In that period, science was generally called "natural philosophy," so by "philosophical experiments" the Justice almost certainly meant what we would call scientific experiments.) Later the same year, Justice Story returned to the same theme in *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391):

This court has already had occasion to consider the clause in question, and upon mature deliberation, it has held that the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. *Whittemore v. Cutter* [Case No. 17,600]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Over the ensuing 175 years, this doctrine has been sporadically referred to, sometimes critically and sometimes approvingly. It has rarely been applied to excuse infringement.⁷ Despite these later references, however, the clearest expositions of the doctrine remain the opinions of Justice Story.

B. Section 271(e)(1) Reflects the Policy Behind The Experimental Use Exception

The realities of modern research and development were recognized by Judge Wexler of the Eastern District

7. The case law is reviewed and commented on by Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. OFF. SOC'Y 617 (1985), and Israelson, *Making, Using And Selling Without Infringing: An Examination Of 35 U.S.C. Section 271(e) And The Experimental Use Exception To Patent Infringement*, 16 AM. INTELL. PROP. L.A.Q.J. 457 (1989).

of New York in *Roche Prods. Inc. v. Bolar Pharmaceuticals Co.*, 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), the original district court case ultimately leading to the enactment of section 271(e)(1):

Bolar's experimentation cannot be classified as merely for amusement or philosophical gratification. At the same time, it cannot be connected with any act of competition or profit during the term of the patent in either domestic or foreign markets. Its experimentation is commercial preparation of a non-production nature for post-expiration competition. In analogous cases this has been held a non-infringing use.

Id., 572 F. Supp. at 257. Generic manufacturer Bolar had begun using a drug patented by Roche to conduct the FDA testing required to begin marketing upon the patent's expiration. Bolar argued that to prohibit FDA testing until after patent expiration would result in a *de facto* extension of that patent for several years, until Bolar could complete all of the required testing, thereby delaying the availability of the generic substitute to the public. Roche countered that it, too, had been required to conduct extensive FDA testing, and that it was, in essence, entitled to such a *de facto* extension as compensation for its lost ability to market during its patent life. The district court attempted to balance the interests of the patentee in being free of competition during the patent term with those of the public in encouraging research activity that will enhance scientific understanding. Judge Wexler reviewed the case law, recognized the limits of the patent right, and found that Bolar's testing constituted experimental use.

[T]he court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes

no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law.

Id., 572 F. Supp. at 258.

On appeal, the Federal Circuit focused only on the ultimate commercial objective of Bolar, regardless of whether that benefit was to be realized during the patent term, reversed the district court, and held that Bolar's experimental testing was an infringement of the Roche patent. At the time of the decision, the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "PTR Act") was pending before Congress, although without any section corresponding to section 271(e). As a result, the Federal Circuit indicated that Congress could best decide how to balance the competing interests represented by the parties then before it. *Roche*, 733 F.2d at 865.

Thereafter, through the passage of the PTR Act with section 271(e), Congress balanced those interests and substantially remedied the problems resulting from regulatory delays. The remedy, however, is not limited to drugs. Section 271(e)(1) as passed reflects a recognition of the modern realities of medical research, balancing the regulatory delay with extended patent rights while concurrently allowing for certain pre-expiration experimental use as had been recognized by Judge Wexler.

C. The Experimental Use Exception Should Be Broadly Construed In Order To Foster Innovation

The importance of, and ultimate commercial motivation for, much basic research carried on in universities has been very evident in recent years. For example, the

basic techniques on which the rapidly growing biotechnology industry is built originated in university research facilities and were patented by those universities. Another development that has recently come out of university research, for example, and that could have enormous potential for commercial exploitation are high temperature superconductors, which are the subject of pending patent applications. Indeed, Congress has encouraged universities to patent and commercially license inventions made in the course of government funded research.⁸

Except as now overruled with respect to FDA testing of medical products by the enactment of section 271(e), however, the Federal Circuit in *Roche* effectively stated that any commercially-motivated experimental activity would be an infringement regardless of whether or not it interfered with business interests of the patentee in exploiting his invention. Because the complex research demanded by modern technology almost always has a commercial or business objective, albeit remote at times, virtually all research by commercial enterprises can now be enjoined by owners of dominant patents.

The Federal Circuit in *Roche* apparently thought that Justice Story's formulation of the exception was limited to "dilettante affairs." *Id.*, 733 F.2d at 863. This seems inconsistent, however, both with what the learned Justice actually said, and with the understanding of the exception expressed by other leading authorities.⁹ The practical effect of adhering to the

8. Under the 1980 Patent and Trademark Act Amendments, universities must report any potentially patentable invention to the funding agency within a certain time, and may elect to retain most rights to the invention provided a patent application is promptly filed. Therefore, Congress has clearly encouraged the commercial exploitation of university research.

9. See, e.g., 3 ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS, § 898 (1890):

limitations set out in the *Roche* decision would be to tip the balance too far in favor of the patentee. It would give the patent owner too much power to stifle research and development of improvements and it would make designing around a patent a seriously risky business. Such a sterile view of experimental use would provide an affirmative discouragement to innovation and should be directly refuted.

The law should be interpreted so that primary importance is given to the public interest in promoting the progress of science and technology. Among other things, this involves increasing the store of available public knowledge, encouraging scientific research and the development of improved technology, and weeding out invalid patents. On the other hand, inventors should receive the promised reward, the right to be free from competition in the practice of the invention. *Mercoir Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944).

The experimental use exception as set out by Justice Story maintains a fair balance between these two factors. The exception, as carried out by the exemption of section 271(e)(1), should cover every use of the patented invention that is either for research into the nature of the invention itself or for testing the sufficiency of the patent disclosure, provided that neither is done in order to use the invention itself for profit, depriving the patentee of

[A]cts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. . . . But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus, where it is made or used as an experiment whether for the gratification of scientific tests, or for curiosity, or for amusement, the interests of the patentee are not antagonized. . . .

his lawful rewards.¹⁰

IV. Reversal Of The Federal Circuit Decision Will Undermine Rather Than Enhance Research, Development, And Innovation

Petitioner and its amicus partners devote considerable time to the unsupported argument that the Federal Circuit's interpretation of section 271(e)(1) will destroy the incentive of device patentees to innovate. They provide no evidence, however, that medical device developers will be dissuaded from investing in research out of fear that new technology will become available some seventeen to twenty-two years later, after their patents, many of which will have been statutorily extended, expire. There is no such evidence because the Federal Circuit's decision does not lead to any of this imaginary harm.

To the contrary, the decision below fosters innovation. It encourages the original patent holder to innovate further during the patent term if he wishes to maintain, or at least share in, the technological lead. It permits basic experimentation and research by others to begin at a reasonable time into the patent term without the fear that a huge damage award, such as was requested by

10. In the context of section 271(e)(1), existing FDA regulations comport with the traditional experimental use exception while recognizing the realities of modern research. They are designed to ensure that all regulatory testing is limited, experimental, and non-commercial. The FDA prohibits, as improper commercialization, test marketing of a clinical device; charging investigators a price greater than necessary to recover costs of manufacturing, research, development, and handling; and unduly prolonging any investigation. 21 C.F.R. § 812.7. Generally, when the FDA does approve a clinical test plan, it specifies the locations where the investigation may take place, and sets a specific limit on the total number of products or tests that may be run under the IDE (Joint Appendix, pp.91-92). Accordingly, FDA guidelines and procedures are already in place to protect the legitimate rights of patentees by ensuring that regulatory testing is not commercialization.

petitioner here, will result. The deterrent effect of such an award on corporate sponsors would dry up their contributions to academic consultants and research in this country, providing further incentive for the transfer of these corporate research funds overseas.

It is the narrow interpretation of section 271(e)(1) advanced by petitioner that will stifle creativity and reward imitation rather than innovation. If the Federal Circuit decision is reversed, researchers who would otherwise develop new medical devices during the final years of a patent's statutory term will receive less under the patent laws than do drug copiers.¹¹ While generic drug manufacturers can now conduct bioequivalency testing prior to the end of a patent term so as to copy a product already available to the public, device researchers who would otherwise advance the technology in the medical field will be required to await the expiration of an extended patent term. It may not reasonably be assumed that Congress would use the patent laws, whose purpose is to increase the store of public knowledge, *Shaw v. Cooper*, 32 U.S. 292, 314-16 (1833), to encourage copying while delaying technical advances.

In all events, petitioner's major premise for its erosion-of-rights arguments (Petitioner's Brief, pp.28-33) is faulty. Petitioner's argument — that regulatory testing of devices by others is actually marketing and commercialization in disguise, thus discouraging innovation by patent holders — is squarely at odds with the determination made by Congress as to statutory patent term extension. As the reason for its enactment of 35 U.S.C. § 156, Congress determined that the regulatory testing required of certain products, devices as well as

11. Since medical devices cannot be approved on an expedited basis, as can generic drugs, there is no reason for a device developer to provide a "me-too" product. Rather, since all medical devices require a full set of pre-clinical and FDA-clinical tests, researchers are more interested in developing completely new technology.

drugs, effectively prevented the patentee of such products from marketing them. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. I, at 17, *reprinted in* 1984 U.S. CODE CONG. & ADMIN. NEWS 2647, 2650. If this period of regulatory review is not marketing for the patentee, then identical activities undertaken years later by a would-be developer of newer technology cannot logically be either.¹² Petitioner and its amicus partners willingly accepted the "regulatory-review-is-not-marketing" determination by Congress in order to obtain legislative eligibility for statutory patent term extension. They cannot now make a diametrically inconsistent argument to avoid the *quid pro quo* for what they received.¹³

12. Nor could it be seriously contended that the patentee is in a different position from the years-later alleged infringer under the theory that it was a patent right, as opposed to the right to *market* during the patent term, that was being consumed by the regulatory process. Patents themselves do not provide the right to market the invention of the patent claims; they grant only the right "to exclude others" from doing so. 35 U.S.C. § 154. *That* right was not lost to the patentee during the regulatory review period, whether or not he was able to market his own version of the claimed invention during that time.

13. Similarly, petitioner's argument — that, in the case of certain long-lasting devices such as CAT scans, allowing clinical trials could substantially erode the market for the patented device — does not withstand scrutiny. In such a situation, a single machine can be used on many different patients to develop necessary data. Further, with such devices, as with drugs, there is no particular necessity that the person on whom the product is used be sick or otherwise in need of medical care. Accordingly, much testing can be performed with no affect on the market at all.

V. LOGIC AND POLICY COMPEL THE CONCLUSION THAT CONGRESS INTENDED MEDICAL DEVICES TO BE WITHIN SECTION 271(e)(1)

A. Congress' Grant Of Statutory Patent Term Extension For Medical Devices Clearly Indicates That Contemporaneously Enacted Section 271(e)(1) Also Applies To Devices

Congress' contemporaneous enactment of 35 U.S.C. § 156 and 35 U.S.C. § 271(e) and the two facets of public policy to which those sections were directed compel the interpretation that medical devices are encompassed by *both* sections. The PTR Act was intended to correct severe problems caused by the delays inherent in federal regulatory review of certain products — drugs, medical devices, and others. Section 156, the codification of the statutory extension provisions, embodies congressional recognition that regulatory delay affects not only drugs, but also medical devices.

Section 271(e)(1) was enacted with section 156 as part of the same Title II of the PTR Act to provide a balance for statutory patent term extension by allowing the same class of products as covered by section 156 to undergo regulatory testing prior to patent expiration. To limit the infringement exemption of section 271(e)(1) to drugs would destroy that balance by providing patent holders of non-drug products with the ability to delay introduction of competing technologies far beyond the expiration of even their statutorily extended patents.¹⁴

Congress' intention to equalize the scopes of the infringement exemption and statutory extension is reflected in the record of the committee debates. In its

14. Congressional understanding that protracted regulatory review affects devices as well as drugs is indisputably indicated by Congress' restoration of lost patent term to both. H.R. REP. NO. 857, pt. I, at 15, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2648. That same regulatory delay was the cause of the previous *de facto* extension of patents for the same products.

discussion of the constitutionality of the exemption provision, for example, the House Judiciary Committee noted:

In this case the Committee has merely done what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest.²⁰ Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.

²⁰ It is important to note that most patent holders affected by [35 U.S.C. § 271(e)] will also receive a benefit from the bill in the form of patent term extension. This type of exchange of property interest was upheld by the [Supreme Court] in the [*Penn Central Transp. Corp. v. New York City*, 438 U.S. 104 (1978)] case, albeit in a different context.

H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. II, at 30, reprinted in 1984 U.S. CODE CONG. & ADMIN. NEWS 2686, 2714. The coordinated extent of the two provisions is clear. Congress balanced its stimulation of innovation (by the statutory term extension) with furtherance of the public interest (by the testing exemption and consequent elimination of *de facto* extension for patents relating to the same products).

The public interest that Congress intended to protect includes not only the right of the public and medical community to obtain quick access to advanced medical technology, but also the right of others to develop and to commercialize advanced medical devices as soon after expiration of the statutory patent term as possible. These aspects of the public interest would be ill-served, however, under petitioner's narrow revision of section

271(e)(1), which requires the belief that Congress intended to maintain *de facto* extensions for devices and thereby to delay public access to advanced device technology. Petitioner's position attributes to Congress the intention to confer on device patentees the benefit of statutory term extension without the requirement that they relinquish *de facto* extensions in return. It defies both logic and any reasonable view of public policy, however, to assume that Congress would set up a most privileged class of patentees entitled to both extensions when Congress so clearly recognized the detriments of *de facto* extensions. H.R. REP. NO. 857, pt. I, at 46, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2679.¹⁵ This is not what Congress intended.

B. Implementation Of Bioequivalency Testing Procedures For Drugs In One Section Of The PTR Act Did Not Limit The Rest Of The Act To Drugs

Neither petitioner nor any amicus party has delivered on its claims that there are "persuasive reasons" why section 271(e)(1) was intended to be limited to drugs.¹⁶ The primary "reason" advanced — that the

¹⁵ Amici Zimmer and Bristol-Myers Squibb, in support of petitioner Lilly, argue that it is not "credible" that Congress would provide an infringement exemption "without the prompting of anyone supporting makers of generic copies of medical devices" (Zimmer and Bristol Myers-Squibb Brief, p.13). Aside from the fact that there is no class of generic device manufacturers — federal regulations provide no expedited testing procedures for mere copies of medical devices and therefore provide no impetus for the existence of such a class as they do for generic drug makers — this cynical view suggests that Congress acts only at the behest of lobbyists but not simply for the public interest. Petitioner and its supporters are simply unwilling to relinquish the consideration that Congress exacted in return for the granting of statutory extensions.

¹⁶ The Federal Circuit stated below that "no persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical

infringement exemption is tied to the grant of expedited bioequivalency testing for drugs — is plainly inconsistent with both the organization of the PTR Act and the undisputed effect of the enacted statutes.

Title I of the PTR Act established an expedited FDA approval procedure (for “abbreviated new drug applications,” or “ANDAs”) for generic equivalents of previously approved drugs. Title II of the PTR Act added section 156 to the patent laws to permit statutory extension of patents for medical devices, food additives, and color additives, as well as for drugs, all of which are subjected to FDA regulatory delays. Under that same Title II, section 271(e)(1) was enacted. Petitioner and its amici, however, would have this Court interpret section 271(e)(1) of Title II by straight analogy to the bioequivalency provisions of Title I. See, e.g., Brief of Amicus Industrial Biotechnology Association, pp.16-17; Petitioner’s Brief, p.29. Such a comparison is improper. There simply is no reason to interpret the scope of section 271(e)(1) in view of any title of the enacting legislation other than its own Title II. To do so here ignores the remedial balance that Title II was intended to implement when eliminating *de facto* extensions for the same scope of products for which it granted statutory extensions.¹⁷

In all events, the irrelevance of bioequivalency testing to the scope of section 271(e)(1) is underscored by the undisputed inclusion of certain other products

NOTES (Continued)

devices receive the benefit of the companion patent term restoration legislation.” *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

17. The House Energy and Commerce Committee stated: Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. There should be no other direct or indirect method of extending patent term.

H.R. REP. NO. 857, pt. I, at 46, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2679 (emphasis added).

within the exemption that are not entitled to such expedited testing. For example, pioneer new drugs are not eligible for the expedited approval procedures enacted under Title I, but they are clearly entitled to the exemption of section 271(e)(1) for the purpose of developing data on safety and efficacy required under 21 U.S.C. § 355(b)(1) (section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act). Moreover, veterinary biological products, which were added to the exemption in 1988, are also not entitled to any expedited approval procedures under the federal law that regulates them, the Virus-Serum-Toxin Act (the Act of March 4, 1913, Pub. L. No. 62-430, 37 Stat. 832 (1913), codified as amended in 1985 at 21 U.S.C. §§ 151-59)).¹⁸ In this regard, it is significant that these 1988 amendments to the PTR Act made veterinary biological products eligible for statutory extension under section 156 and contemporaneously eliminated *de facto* extensions for those products by adding them to section 271(e)(1) — modifying the related Title II sections of the PTR Act — *but did not authorize any expedited testing procedures analogous to the Title I provisions*. Accordingly, the argument that eligibility for bioequivalency testing somehow determines the scope of section 271(e)(1) is without merit.

Equally unimportant to the interpretation of section 271(e)(1) are the drug-specific limitations in some of the other sub-sections of section 271(e). For example, petitioner incorrectly relies on the infringement provision of section 271(e)(2), which makes it an act of infringement for a generic drug manufacturer to submit an ANDA with a requested approval date prior to patent expiration. Petitioner suggests that the absence of an analogous

18. Veterinary biological products were added to both section 271(e)(1) and to section 156 by the Generic Animal Drug And Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

provision for medical devices, which would make submission of a pre-market approval application an act of infringement, is somehow evidence that medical devices are not entitled to the exemption (Petitioner's Brief, pp.17-18). This, however, ignores the fact that the submission of a New Drug Application under 21 U.S.C. § 355(b)(1) (that is, one not submitted as a generic copy of a previously approved drug) is also not designated to be an act of infringement under sub-section (e)(2), but such new drugs are undeniably included within section 271(e)(1). The attempt by petitioner and its amicus supporters to interpret section 271(e)(1) by analogy to express limitations in other sections of the statute fails.¹⁹

CONCLUSION

The decision by the Court of Appeals for the Federal Circuit should be affirmed. Through co-extensive sections 156 and 271(e)(1), Congress constructed a careful balance to stimulate innovation through statutory patent term extension and to further the public interest by eliminating *de facto* extensions that serve only to postpone the ability of others to advance the patentee's original contribution and therefore delay the public's access to advanced technology. That balance, and the reasons behind it, apply to all medical products. Upsetting that balance here will cause substantial harm to United States research and development efforts.

19. Petitioner incorrectly cites and quotes out of context *Eli Lilly and Co. v. Premo Pharmaceutical Labs.*, 4 U.S.P.Q.2d 1080 (D.N.J. 1987), *aff'd*, 843 F.2d 1378 (Fed. Cir. 1988), and *Scripps Clinic and Research Found. v. Genentech Inc.*, 231 U.S.P.Q. 978 (N.D. Cal. 1986), for the proposition that sub-section (e)(2) "limits the scope of" or "qualifies" subsection (e)(1) with respect to the products that are included (Petitioner's Brief, p.17). Those cases do *not* address the question of what products are exempt, but rather what *acts* are "solely for uses reasonably related to the development and submission of information" to the FDA. The cases simply do not support the proposition for which petitioner cites them.

This Court should further confirm that there is an exception to the patentee's exclusive rights to allow making and using for experimental purposes. This exception should be broad enough to cover activities that are designed to elicit information about the patented invention and its underlying principles, whether for basic research, to develop improvements, or to design around the patent claims, and to test its sufficiency, regardless of any commercial motivation for the activities. Such an exception would encourage the efficient progress of science and the useful arts, while giving to the patentee the reward that promised by the patent system. It would encourage university research and facilitate the rapid improvement of American technology.

For all of the above reasons, amici curiae respectfully urge this Court to affirm the decision below.

Respectfully submitted,

WILLIAM P. DONOHUE
Counsel of Record
 UNIVERSITY OF MINNESOTA
 330 Morrill
 100 Church Street S.E.
 Minneapolis, MN 55455
 (612) 624-4100

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IN THE
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ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

**BRIEF OF AMICUS CURIAE
THE AMERICAN ASSOCIATION OF RETIRED PERSONS
IN SUPPORT OF RESPONDENT**

Of Counsel:

STEVEN ZALEZNICK
MARY CHERYL MATHEIS
AMERICAN ASSOCIATION
OF RETIRED PERSONS
1909 K Street, N.W.
Washington, D.C. 20049

JAMIE S. GORELICK
(Counsel of Record)
JONATHAN B. SALLETT
MICHAEL J. BARTA
MILLER, CASSIDY, LARROCA & LEWIN
2555 M Street, N.W., Suite 500
Washington, D.C. 20037
(202) 293-6400

*Counsel for Amicus Curiae
The American Association
of Retired Persons*

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BRIEF OF AMICUS CURIAE
THE AMERICAN ASSOCIATION OF RETIRED PERSONS
IN SUPPORT OF RESPONDENT

INTEREST OF THE AMICUS CURIAE

The American Association of Retired Persons ("AARP" or "the Association") is a not-for-profit membership organization operated exclusively for the social welfare of its 30 million members. It meets those members' diverse needs by providing a range of services including educational programs, informative publications, opportunities for volunteer service, special member benefits and discounts, as well as representation of the con-

cerns of older Americans before legislative, administrative and, where appropriate, judicial bodies.

AARP has long been an active proponent of legislation designed to increase public access to high quality, low cost health care. As such, the Association was actively involved in the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984.

The market for medical devices, and health care in general, is not precisely like any other. Because the consumption of health-care services, drugs and medical devices is usually not discretionary and because government directly pays for a large percentage of health-care services and goods, significant regulatory control over pricing and marketing inevitably exists.

Competitive forces do, nonetheless, play an important role in the development and availability of medical devices. Congress has long presumed that more competition would lead to lower prices and better products. That belief is at the center of this case.

AARP stands as a representative of millions of health-care consumers and older Americans who have a vital interest in maintaining access to the best and least costly medical devices. In this case, the interest of those consumers—and the express intent of Congress—will be vindicated only by affirmance of the lower court decision.

SUMMARY OF ARGUMENT

Both the patent laws and the Food, Drug and Cosmetic Act ("FDCA") are designed to benefit American consumers. The patent laws promote investment in research that results in innovation, while limiting the duration of monopoly power. The FDCA protects consumers from unsafe and ineffective medical drugs and devices by requiring governmental approval before new drugs and devices can be marketed. Together, the FDCA and the

patent laws work to ensure that scientific advances will be readily and safely available to Americans in need of medical services.

This case turns on the interplay between the patent laws and the FDCA and, like those laws generally, this case demonstrates Congress' desire to benefit consumer interests and "[o]lder Americans, in particular." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17. In 1984, Congress recognized that a fundamental underpinning of the patent laws—the premise that all competitors have free and equal access to the marketplace—does not exist when the government delays market entry in order to ensure the safety and effectiveness of drugs and devices.

Section 271(e)(1) and Section 156 of the patent laws represent Congress' effort to ensure that all manufacturers of medical devices play by the same competitive rules. Patent holders are permitted an extension to ensure that their effective period of patent protection, and thus their incentive for research and innovation, is not impaired by regulatory delay imposed by the FDCA. Other competitors are permitted to test patented products during the patent period so that they will be ready to compete once the patent monopoly ends. That principle might be called the "market entry rule" because it ensures that the regulatory burden on market entry will not distort patent principles. The net effect of applying the rule to all market participants: The necessary FDA review for safety and effectiveness will not interfere with the competitive balance established by the patent laws and will, therefore, maintain the patent laws' primary goal of benefiting consumers.

The contrasting view—espoused by Lilly and its supporting *amici*—would apply this market entry rule to medical devices only part of the time and then only to the advantage of patent holders. It would permit the holder of a medical device patent to exclude competition not only for the length of an ordinary patent term, and

for an additional statutory term equal to the amount of time required to obtain FDA approval, but also for an additional, *de facto*, period while competitors attempt to test and secure FDA approval of their devices. Throughout this extended period consumers would be deprived both of the benefits of price competition for the original device and of innovations creating an improved version of the device.

Review of the express language, purpose and legislative history of Section 271(e)(1) demonstrates that the statute is not so narrow as Lilly contends. Thus, the lower court decision must be affirmed so that the intended beneficiaries of the Act—American consumers—receive the benefits of competitive innovation.

ARGUMENT

This *amicus* brief will not repeat the careful analysis of statutory language set forth in Medtronic's submission. Rather, AARP will focus on the structure and purpose of congressional action in order to show that Lilly's reading of congressional intent is unsupported. An accurate understanding of the policy goals implemented by Section 271(e)(1) demonstrates that Congress endeavored to create a level-playing field for all manufacturers of medical devices and, by so doing, to benefit the public. Because the starting point of statutory construction must be the language of the statute itself, this *amicus* brief will begin, however, with a brief discussion of the statutory words at issue here.

I. THE FEDERAL CIRCUIT'S DECISION WAS COMPELLED BY THE PLAIN LANGUAGE OF THE STATUTE

First, a line-by-line analysis of Section 271(e)(1) leaves no doubt that it applies to medical devices. In pertinent part, Section 271(e)(1) provides:

It shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

The medical devices at issue are "patented invention[s]," *cf.* 35 U.S.C. § 100(a), that are regulated by the Food, Drug, and Cosmetic Act, *see* 21 U.S.C. § 351 *et seq.*, which is, as Section 271(e)(1) requires, "a Federal law which regulates the manufacture, use, or sale of drugs." *See id.*

Second, there is an obvious reason why Congress referred generally to "a Federal law which regulates . . . drugs" rather than specifically to the FDCA. In 1984, there were at least three federal laws which regulated the manufacture, use, or sale of drugs: the FDCA (which regulates certain drugs and devices); the Act of March 4, 1913, 21 U.S.C. §§ 151-58 (relating to viruses, serums, toxins, and analogous products intended for veterinary uses); and the Public Health Service Act of 1944, 42 U.S.C. § 262 (relating to viruses, serums, toxins, and analogous products intended for humans). *See also* Brief of *Amici Curiae* Zimmer, Inc. *et al.*, at 4 (Nov. 24, 1989). The reference to "a Federal law" simply indicates Congress' understanding that it was formulating a description applicable to more than one law.

Third, Lilly's interpretation of the phrase "a Federal law which regulates the manufacture, use, or sale of drugs" makes no sense. The phrase cannot, as argued, refer solely to 21 U.S.C. § 355, *see* Brief for the Petitioner at 10, because that section applies only to "new drug[s]," a category from which "new animal drug[s]" are excluded by definition. *See* 21 U.S.C. § 321(p). The *exception* for new animal drugs in section 271(e)(1) would have been unnecessary if section 271(e)(1) only applied,

in the first instance, to human drugs regulated under section 355.¹ The Lilly argument thus fails to construe the statute so as to give effect to all of its provisions. See *United States v. Menasche*, 348 U.S. 528, 538-39 (1955). The only reasonable conclusion is that "a federal law" refers to the FDCA and the previously cited Acts of 1913 and 1944.

II. SECTION 271(e)(1) IS PART OF A LEGISLATIVE PLAN DESIGNED TO TAILOR TRADITIONAL PATENT POLICIES TO THE REGULATORY CONTEXT IN WHICH MEDICAL DRUGS AND DEVICES ARE SOLD

Because the plain language leaves no doubt that Section 271(e)(1) applies to medical devices, the Court need look no further. See *United States v. James*, 478 U.S. 597, 606 (1986). Lilly, however, makes the additional argument that legislative policy would be contravened by applying Section 271(e)(1) to medical devices.

Lilly is wrong. An accurate understanding of the policy goals implemented by the 1984 Act demonstrates that Congress wished to establish a comprehensive scheme meshing patent and regulatory policies to assure consumers meaningful access to beneficial medical innovations that are safe and effective. This purpose can be achieved only if Section 271(e)(1) is applied to medical devices.

A. Congress Wished to Eliminate the Impact of Regulatory Delay on the Marketing of Medical Devices

The Drug Price Competition and Patent Term Restoration Act represents a carefully-crafted congressional

¹ As originally enacted, Section 271(e)(1) provided: "It shall not be an act of infringement to make, use, or sell a patented invention (*other than a new animal drug or veterinary biological product* (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added).

response to the problem of applying traditional patent rules in a regulatory context. As the drafters of the Act were aware, federal patent law balances two competing values. On one hand, it encourages research and development by rewarding innovators with a statutorily-protected monopoly for a defined term of years. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17. On the other hand, it encourages subsequent improvements and makes available the fruits of innovation to consumers by ending the statutory monopoly and allowing competition to enter the field. *Id.* at 46. The goal is to make the statutory monopoly long enough to encourage innovation adequately, but not so long as to delay the benefits of competition unnecessarily.

Because the patent laws presume free market entry, the period of patent protection is normally equal to the period of monopoly profit. Thus it is assumed that the patent holder will be able to profit from its invention from the inception of its patent term and that competitors will be able to move in as soon as the patent term expires.

In 1984, Congress recognized that market entry is restricted in a regulatory context. *First*, the original patent holder needs time to complete testing and obtain regulatory approval, so that the 17-year right to exclusive exploitation may permit many fewer years of monopoly profit—a period perhaps too short to reward innovation adequately. *Id.* at 17-18; H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. II at 6. *Second*, after the patent expires, competitors, not unlike the original patent holder, will need time to conduct testing and obtain regulatory approval of either an improved or a substantially identical version of the patented item, so that the benefits of competition may be delayed many years beyond the statutory right to exclusive exploitation. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 46.

Congress might have declined to act, hoping that the regulatory delays on each end of the patent term would cancel each other out, leaving a *de facto* term of monopoly profit fairly approximating the patent period. But Congress opted against leaving the competitive policies of the patent laws subject to the unpredictabilities of the FDA regulatory process. Instead, it applied a market entry rule to *both* ends of the patent term. *First*, the rule compensates the original innovator for any delay in market entry by allowing him to recover the amount of time required to obtain FDA approval at the end of his patent term. See 35 U.S.C. § 156. *Second*, the same rule is applied to competitors by permitting limited use of patented inventions in order to secure FDA approval, so that competition can begin immediately upon the termination of the patent. See 35 U.S.C. § 271(e)(1). In this way, the market entry rule guarantees that FDA regulation does not distort the competitive balance crafted by traditional patent principles. Consumers are thus served by the combination of three important policy goals: the development of new medical innovations, meaningful access to the new products, and protection from unsafe and ineffective products.

Accordingly, the 1984 Act modifies traditional patent law rules only to accommodate the realities of FDA regulation while leaving the underlying principles intact. This accommodation of competing values was not, as Lilly and its *amici* suggest, a mere trade-off among various elements of the drug industry, but a broader attempt to reconcile the policies of patent law with FDA regulation and to benefit the public through the increased availability of safe, effective, and innovative medical products.

B. Applying the New Scheme to Only Patent Holders of Medical Devices Would Distinguish Between Market Entrants in Violation of Congress' Clear and Explicit Intent

Lilly asks the Court to adopt an interpretation which would grant Lilly a benefit, but deny the corresponding benefit to its likely competitors.

Entities that hold patents to medical devices are clearly entitled to invoke the patent-term extension provisions of the Act. See 35 U.S.C. §§ 156(f)(1), 156(g)(3). Lilly itself has received the benefits of this provision through the extension of one of the patents at issue in the case. It is now asking this Court to grant it an additional *de facto* extension by barring innovators from experimentation until the patent term is over, thus potentially delaying for many years the commercial availability of a competing product.

No indication exists that Congress intended to favor some competitors with such a double patent extension, and every indication exists that it did not. As the statutory treatment of both drugs and veterinary products demonstrates, see Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988), where Congress departs from the traditional concept of a 17-year right to exclusive exploitation, it does so only for the purpose of more carefully defining the underlying right to an effective, but strictly limited, term of monopoly profit. Granting Lilly's request would pervert this clearly expressed policy by providing patent holders with a windfall. More importantly, such an interpretation would run counter to the public policy of the patent laws by forcing consumers to suffer the burden of delay in market competition. The 1984 Act was an expression of Congress' explicit intent to relieve consumers of that burden.

The report of the House Committee on Energy and Commerce commenting on Section 156 states that

"[t]here should be no other direct or indirect method of extending patent term." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 46. Lilly's reading would create an indirect method of patent extension through an artificially narrow reading of Section 271(e)(1). To achieve the true congressional purpose, therefore, the lower court correctly read Section 271(e)(1) to apply along with Section 156 to medical devices.

C. Lilly's Arguments Based on the Differences Between Drugs and Medical Devices Are *Post Hoc* and Factually Incorrect

Lilly argues that differences in the regulatory schemes applicable to drugs and medical devices justify disparate treatment. Lilly focuses on 21 U.S.C. § 355(j), which provides that a generic version of an innovator drug may be approved for commercial marketing through an abbreviated process focusing primarily on whether the two drugs have the same rate and extent of absorption, a test that can often be made on healthy individuals.

Seizing on the existence of this abbreviated procedure, Lilly contends that drug testing will not impair the market of a patent holder even while the patent is in effect. But, Lilly contends, the testing of medical devices inevitably requires testing on the same individuals who would otherwise be using the patented product. From this Lilly concludes that Section 271(e)(1) is limited to drugs because, it is said, Section 271(e)(1) was not intended to permit testing on potential customers of the patent holder's product.

As an initial matter, the Lilly contention is beside the point because it was never made to Congress. No evidence exists in the legislative history that Congress was aware of a distinction in the regulatory schemes applicable to drugs and medical devices, much less of a distinction relevant to the meaning of Section 271(e)(1). Statutes cannot be interpreted on the basis of mere

assertions not presented to Congress at the time of enactment. See *United States v. Wise*, 370 U.S. 405, 411 (1962).

Aside from the fact that the argument was never presented to Congress, it is factually incorrect. Lilly misstates the scope of both drug and device testing, which are legally and factually quite similar.

Drug Testing. The FDA drug approval process may well require testing on the patent holder's potential customers. See 21 U.S.C. § 355(d). A drug manufacturer wishing to obtain approval of a drug that uses a patented drug but that varies one or more of the active ingredients may seek approval under the abbreviated process established by 21 U.S.C. § 355(j). However, "[i]f the FDA finds that safety and effectiveness testing of the active ingredients of the drug, individually or in combination, is required, then the FDA must deny the petition." H.R. Rep. No. 857, 98th Cong., 2d Sess. pt. I at 23. See 21 U.S.C. § 355(j)(3). In that case, the standard process of new drug approval must be used, which generally requires experimental proof that "the drug will have the effect it purports or is represented to have under the conditions of use prescribed. . . ." 21 U.S.C. § 355(d) (emphasis added). In other words, testing must be done on those suffering from the condition that the drug is designed to treat. Cf. 21 C.F.R. § 314.50(d)(2) (requiring the submission of results of *in vitro* studies of "the pharmacological actions of the drug in relation to its proposed therapeutic indication").

Even when the abbreviated process is available, ethical restrictions may require testing on potential customers of the patent holder. See 21 C.F.R. § 320.25(a)(3). Drugs with toxic side-effects, like AZT and certain cancer drugs, could not be given to persons who do not stand to benefit from the drug. See also Brief of *Amici Curiae Zimmer, Inc. et al.*, at 15 n.21 (Nov. 24, 1989).

Congress understood that drug testing could be a lengthy process. There would be little purpose to Section 271(e)(1) even as applied to drug testing if Congress had believed that all drugs could come to market quickly through an abbreviated process. Section 271(e)(1) exists precisely because Congress did not wish regulatory delay to create a *de facto* extension of the patent term. See text at pp. 9-10 *supra*. Thus, the first attempt to distinguish drug from device testing fails.

Medical Device Testing. Lilly's argument is even more overstated with regard to medical devices, the vast majority of which are tested under expedited procedures that, like the abbreviated process available for most generic drugs, do not eat into the market share of the patent holder. The FDCA groups medical devices into three categories. Class I devices are the least risky to human health and are subject to only general controls such as the requirement of sanitary packaging. See 21 U.S.C. §§ 360c(a)(1)(A), 351(a)(2). Class II devices are those of intermediate risk and thus are subject to FDA performance standards. See 21 U.S.C. §§ 360c(a)(1)(B), 360d. Finally, Class III devices, presenting the greatest risk to human health, are subject to an elaborate process of premarket review in which experimental proof of safety and efficacy is generally required. See 21 U.S.C. §§ 360c(a)(1)(C), 360e(d); 21 C.F.R. § 814.

The FDCA provides that devices introduced into interstate commerce after May 28, 1976, will generally be classified as Class III devices, and will therefore be subject to the premarket approval process. 21 U.S.C. § 360c(f)(1). However, a new device is exempted from the premarket approval process if it (i) is "within a type of device" that was on the market before May 28, 1976, or which has entered the market since then and has been classified as either Class I or II, and (ii) is "substantially equivalent to another device within such type." *Id.* See also 21 C.F.R. § 814.1(c)(1). In order to take

advantage of this exception, a device manufacturer need only submit a premarket notification setting forth information from which the FDA can determine 90 days before the device is marketed whether the device satisfies the substantial equivalence test. 21 U.S.C. § 360(k); 21 C.F.R. § 807.87.

The "substantial equivalence" process is in effect nothing more than a recognition that there are also "generic" medical devices. Under the FDCA, treatment of generic drugs and generic medical devices is similar because, in both circumstances, the premarket approval process is limited to the issue of whether the pioneer and the generic are really the same. "Well over 98 percent of the new [medical] devices that enter the market each year do so by claiming substantial equivalence, rather than going through premarket safety and effectiveness reviews." Medical Devices and Drug Issues: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 100th Cong., 1st Sess. 332 (1987). The percentage of new drugs that enter the market through the analogous streamlined process is virtually identical. See *id.* at 291. The prevalent use of the abbreviated process for medical devices thus disproves the second facet of Lilly's depiction of drug and device testing. The approval process for medical devices does not always—or even often—require testing on potential customers of the patent holder. Nonetheless, devices that are truly innovations—like the defibrillator Medtronic claims to be developing—must use lengthier approval procedures just as new drugs and certain generics must use the lengthier drug approval process. Thus, as Congress understood in 1984, FDA regulation and its impact on patent policy affects medical devices as it affects drugs. See H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. I at 17.

The close similarity between the approval process for drugs and medical devices reinforces the conclusion that

Congress dealt with both by establishing in both cases a new "market entry" rule that applies equally to patent holders and their competitors.

III. THE LEGISLATIVE AND REGULATORY HISTORY SUPPORTS THE FEDERAL CIRCUIT'S INTERPRETATION OF SECTION 271(e)(1)

Against the language and purpose of Section 271(e)(1), Lilly relies on legislative history. For three reasons, however, that reliance is inadequate to show an intent to treat medical devices in a separate fashion.

First, Congress has always treated drugs and devices together. The original Food, Drug, and Cosmetic Act of 1938 contained a separate subchapter entitled "DRUGS AND DEVICES." June 25, 1938, c. 675, § 501, 52 Stat. 1049. That subchapter can be found today at 21 U.S.C. §§ 351-360ee, with the same title in place. Drugs and devices remain the only products regulated under that subchapter and, in fact, the first two sections of the subchapter, which bar consumer fraud, refer expressly to "drugs and devices." See 21 U.S.C. §§ 351 and 352. Because Congress gave no indication that it intended to sever this historical association of drugs and devices, the Court must presume that it continues in section 271(e)(1). See, e.g., *Moragne v. States Marine Line, Inc.*, 398 U.S. 375, 392 (1970) ("It has always been the duty of the common-law court to perceive the impact of major legislative innovations and to interweave the new legislative policies with the inherited body of common-law principles—many of them deriving from earlier legislative exertions.").

Second, Lilly argues, in support of its contrary reading of legislative history, that the brand name and generic drug industry trade associations were the most active advocates of the 1984 Act. But the accuracy of that assertion is, in the true evidentiary sense, irrelevant. Congressional intent is not found by surveying the prom-

inence of private interests. Congress represents the public. The "compromise" embodied in Sections 156 and 271(e)(1) took place with the public interest in mind and serves that public interest—by applying the same market entry rule to all device manufacturers.

Third, the fact that the legislative history of Section 271(e)(1) fails to discuss medical devices does not suggest that they were meant to be excluded. See *Pittston Coal Group v. Sebben*, — U.S. —, 109 S. Ct. 414, 420-21 (1988) ("It is not the law that a statute can have no effects which are not explicitly mentioned in the legislative history. . ."). Although the legislative history of the patent term restoration provision of Section 156 also focuses almost exclusively on drugs, all parties acknowledge Section 156 applies to medical devices as well.² That is because, in that circumstance as well as here, the express statutory language controls.

CONCLUSION

In sum, the Federal Circuit's decision is the only outcome that upholds the public policy of the patent laws to foster innovation for the benefit of society. This was Congress' goal in enacting the 1984 Act, and any other

² For example, in its Summary of the Bill, the Judiciary Committee's report states: "The 'Drug Price Competition and Patent Term Restoration Act of 1984' (H.R. 3605) consists of two titles which affect introduction procedures and patent requirements for certain kinds of generic new *drugs*." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. II at 9 (emphasis added). The report continues: "Title II of the bill [which includes Sections 156 and 271(e)(1)] encourages *drug* manufacturers to assume the increased costs of research and development of certain products which are subject to premarketing clearance by restoring some of the time lost on patent life while the product is awaiting FDA approval." *Id.* (Emphasis added). By contrast, the report specifically mentions medical devices only in connection with a line-by-line analysis of Section 156. Thus, even where medical devices were expressly included within the statutory language, the narrative portions of the report referred only to drugs.

interpretation undermines that goal. The plain language of the statute, its underlying public policy, and the legislative and regulatory history all point to the same conclusion: The decision of the Federal Circuit must be affirmed.

For the foregoing reasons, the American Association of Retired Persons respectfully requests this Court to affirm the decision of the Federal Circuit.

Respectfully submitted,

Of Counsel:

STEVEN ZALEZNICK
MARY CHERYL MATHEIS
AMERICAN ASSOCIATION
OF RETIRED PERSONS
1909 K Street, N.W.
Washington, D.C. 20049

JAMIE S. GORELICK
(Counsel of Record)
JONATHAN B. SALLET
MICHAEL J. BARTA
MILLER, CASSIDY, LARROCA & LEWIN
2555 M Street, N.W., Suite 500
Washington, D.C. 20037
(202) 293-6400

*Counsel for Amicus Curiae
The American Association
of Retired Persons*

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IN THE
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ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF OF CARBON IMPLANTS INCORPORATED AS
AMICUS CURIAE IN SUPPORT OF RESPONDENT

MICHAEL M. PHILLIPS
*Counsel of Record
for Amicus Curiae*

515 N. Velasco St.
P.O. Box 1030
Angleton, Texas 77516
(409) 849-4382

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**ON WRIT OF CERTIORARI
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FOR THE FEDERAL CIRCUIT**

**BRIEF OF CARBON IMPLANTS INCORPORATED AS
AMICUS CURIAE IN SUPPORT OF RESPONDENT**

INTEREST OF AMICUS CURIAE

Carbon Implants Inc. ("CII") is a fledgling medical device manufacturer which was formed in May 1989. CII's business presently is not affected by the application of 35 U.S.C. § 271(e)(1) to medical devices. However, CII is concerned with the chilling effect on innovation in the medical device industry if the decision by the Court of

Appeals below is reversed. Therefore, CII submits this brief in support of Respondent Medtronic, Inc.¹ CII has obtained the consent of both parties to the filing of this brief.

CII was formed to provide the public with an improved medical device which is critical to the survival of many people in the world today — the replacement heart valve. The ability of the valve to function without failure is essential. If it fails, the person will die. Because of the critical nature of the heart valve, it is subject to the Food and Drug Administration's ("FDA") most rigorous and lengthy approval process.

In the decision below, the Court of Appeals for the Federal Circuit correctly found that the infringement exemption of 35 U.S.C. § 271(e)(1) applies to medical devices. Specifically, the court found that a medical device being tested for uses related to obtaining FDA approval is exempted from any liability for patent infringement.

CII believes that a contrary result would decrease innovation in the medical device industry because of the consequent detrimental impact on small start-up companies. Start-up companies are often formed to develop improvements to existing technology which, in some cases, is patented. Those start-up companies might never be formed if they are not allowed to avail themselves of the section 271(e)(1) infringement exemption. Since they could not begin the FDA approval process until after any relevant patent expired, they would be unable to market their improvements to the public until years after the patent expired. That delay could be a major disincentive to the formation of new medical device companies. Without those start-up

¹ Subsequent to the formation of CII, Medtronic Inc. provided funds to CII for technology development and acquired a nonvoting minority equity interest in CII.

companies, the medical device industry will lose a major source of innovation.

Similarly, the public would be harmed by the added delay in getting the improved device to the public. Therefore, CII urges this Court to affirm the Court of Appeals' decision below.

STATEMENT

The Nature Of A Mechanical Heart Valve

CII's replacement mechanical heart valve is designed to replace either the aortic valve or the left atrioventricular ("mitral") valve which may become damaged due to old age or certain illnesses. Those valves insure that blood being pumped out of the heart does not flow back into the heart. A person will die almost instantly if the blood reverses its flow into the heart.

The CII heart valve has a unique bileaflet design. Basically, the valve is a thin ring with two hinged louvers which open to allow blood flow out of the heart and close to prevent backflow into the heart. The valve also is designed to minimize any disruption which the valve might cause to the dynamics of the blood flow.

CII's replacement heart valve is classified as a Class III medical device under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360(c). Class III medical devices are those devices which are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or . . . presents a potential unreasonable risk of illness or injury." *Id.* In view of their critical nature, it is not surprising that those devices must undergo a rigorous premarket ap-

proval process. *Id.* CII anticipates that the approval process for its heart valve will be long and arduous.

The FDA Approval Process For A Heart Valve Manufacturer

The approval process is basically divided into three parts — preclinical research, clinical investigation and approval by the FDA of a Premarket Approval Application ("PMA"). As discussed below, the preclinical research is necessary to obtain the FDA's approval to conduct the clinical investigation which involves people. The clinical investigation, in turn, is needed to support the PMA. An approved PMA is required before the device can be marketed to the public. See D. Kessler, S. Pope and D. Sundwall, *The Federal Regulation of Medical Devices*, 317 New England J. of Med. 357 (1987) (hereinafter Kessler).

The preclinical research involves rigorous *in vitro* or bench testing of the device in a laboratory and implanting of the device in animals. In the case of CII's heart valve, the *in vitro* testing is designed to evaluate the valve's mechanical operability and reliability before it is implanted in a person. One *in vitro* test will be flow testing. Simulated blood will be circulated through all of the valve sizes (about six) under varying conditions to determine the flow pattern of the blood through each valve size. Assuming no major problems, this procedure normally takes from six months to one year.

A second *in vitro* test will be durability testing. Multiple stations will be set up in a laboratory to cycle the heart valve 600 million times which would be equivalent to fifteen years

of heart beats. Thirty-six² valves likely will be tested to assure that the results are reliable. If there are no problems, this procedure should last about one and one-half years. However, if problems are encountered, the period can easily increase to two and one-half years.

Running concurrently with the *in vitro* testing will be the animal testing. The valve is anticipated to be implanted in four sheep to determine its operability in a living body. Two to three years can easily be consumed during this preclinical research.

The data gathered from the preclinical research will be used to support an application to the FDA for an Investigational Device Exemption ("IDE"). The IDE must be obtained before the device can be distributed and implanted in people for the clinical investigation. Kessler, *supra* at 360.

The FDA closely regulates the clinical investigation by virtue of the IDE. The application for the IDE must include, for example: (1) a description of the manufacturing methods for the device; (2) a list of all proposed medical investigators, i.e., the surgeons who will implant the valve and monitor its performance; (3) if the device is to be sold, an explanation of why the sale does not amount to commercialization of the device; and (4) a complete investigational plan. 21 C.F.R. § 812.20. The investigational plan must include, among other things: (1) the duration of the investigation; (2) a written procedure for monitoring the investigation; (3) a copy of the materials used to obtain a patient's informed consent; and (4) a description of the

² There are thirty-six valves because: the CII replacement valve can replace two (2) different valves (the mitral valve and the aortic valve); three (3) sizes are tested for each type of valve; and six (6) replacement valves are tested for each size.

patient population, including the number, age, sex and condition. 21 C.F.R. § 812.25.

Assuming there are no significant problems, the clinical investigation typically lasts two and one-half to three years.

After the clinical investigation is completed, the PMA will be prepared and submitted to the FDA. The FDA has 45 days to advise the applicant whether the application has been accepted and filed for a substantive review. 21 C.F.R. § 814.42. After that, the FDA is required to approve or deny the application within 180 days. 21 C.F.R. § 814.40. However, in practice, the FDA takes an average of a year to approve the PMA. Kessler, *supra* at 359. That period can be substantially extended if the FDA requests additional data from the applicant.

From the above discussion, one can see that the FDA approval process for a Class III medical device, such as an improved heart valve, can easily take from six to seven years.

SUMMARY OF ARGUMENT

Where a patent covers a medical device which must be tested for purposes of obtaining approval by the Food and Drug Administration, that testing should be allowed as either: (1) a noninfringing experimental use; or (2) an activity exempted from infringement under 35 U.S.C. § 271(e)(1).

The experimental use defense allows a person to experiment with a patented invention as long as the experimentation does not deprive the patentee of his lawful rewards. Testing of medical devices for FDA approval purposes falls within the requirements of that defense. The preclinical research step mainly involves laboratory testing of the device

with some testing of the device in animals. Since no sales occur and no people are involved, the preclinical research does not affect the financial rewards the patentee can realize.

The clinical investigation stage of the testing is also a noninfringing experimental use. The investigation is done to collect data to convince the FDA of the safety and efficacy of the device. The FDA's regulations ensure that the clinical investigation is not commercial in nature. For example, the duration and size of the investigation are closely monitored. Therefore, any commercial effect on the patent owner is *de minimis* and should not transform the clinical testing from being an experimental use into a potentially infringing commercial use.

Even if the FDA testing is found not to be an excusable experimental use, CII believes that Congress has obviated the need for medical device manufacturers to rely on that defense to infringement. 35 U.S.C. § 271(e)(1) creates a specific infringement exemption for testing of medical devices for purposes of obtaining FDA approval.

Lilly's assertion that medical devices do not come within the section 271(e)(1) infringement exemption is unfounded in view of the statutory scheme of Congress. Congress enacted 35 U.S.C. §§ 156 and 271(e)(1) concurrently to correct the adverse effect the lengthy FDA regulatory process had on the patent system. The two statutes act in unison. Section 156 enables the patent owner to restore part of the patent term effectively lost during the approval process. Section 271(e)(1) enables the public to conduct FDA testing during the term of any applicable patents so that the public can receive the full benefit of the patent disclosure at the expiration of the patent and so that the patent monopoly is not wrongfully extended. Any doubt

that section 271(e)(1) applies to medical devices is eliminated by the fact that section 156 clearly applies to medical devices.

Congress would not have permitted medical device patentees effectively to obtain one extension of the patent term under section 156 and a second extension due to the period that competitors would consume in getting FDA approval. Under Lilly's view, Congress enlarged the patent grant for medical device patentees without any concomitant benefit to the public. Such a construction of section 271(e)(1) would mean that Congress acted contrary to the grant of the patent power as set forth in the Constitution.

ARGUMENT

I. Testing Of Medical Devices For FDA Approval Purposes Is Noninfringing Experimental Use

A. The Goal Of The Patent System Is To Promote The Progress Of The Useful Arts

The constitutional goal of the patent system is "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const., art. 1, sec. 8, cl. 8; *Graham v. John Deere*, 383 U.S. 1, 5 (1966). That grant of federal patent power "reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and the useful Arts'." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 109 S. Ct. 971, 975 (1989). Congress may not ignore the standard expressed in the Constitution and must exercise its power within those limits. *Graham*, 383 U.S. at 6.

Congress chose to carry out the goal of the Constitution by providing "the limited grant of the patent monopoly in return for the full disclosure of the patented invention and its dedication to the public on the expiration of the patent." *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945). The limited and temporary grant of the patent monopoly was never designed for the inventor's exclusive profit or advantage; rather, the primary object was the benefit to the public or community at large. *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859); see also, *Mercoird Corp. v. Mid-Continent Inc. Co.*, 320 U.S. 661, 665 (1944) ("The public interest is dominant in the patent system."). Therefore, Congress may not "enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby." *Graham*, 383 U.S. at 6.

B. The Experimental Use Defense To Infringement Furthers The Goal Of The Patent System

The experimental use defense was first enunciated by Justice Story in 1813. He recognized that the legislature, in enacting the patent statute, could never have intended to punish one who constructed an infringing machine for "philosophical purposes" or "for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813)(No. 17600). Less than six months later, Justice Story clarified the experimental use exception in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813)(No. 12,391), stating that:

[T]he making of a patented machine to be an offence within the purview of [the infringement clause], must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.

Whittemore v. Cutter [Case No. 17,600]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Id. at 555. The fundamental inquiry of the defense is whether the experimentation will deprive the owner of the lawful rewards of his discovery.

The soundness of Justice Story's analysis is supported by the manner in which Congress designed the patent system. The patent laws require a full and complete disclosure of the invention so that any person skilled in the art may make and use the invention. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 481 (1974). In exchange for that disclosure, "the Federal Government is willing to pay the high price of seventeen years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art." *Id.* Upon expiration of the patent, the public is enabled to practice it and profit by its use. *Id.* In other words, the *quid pro quo* for the patent grant is the disclosure of the invention in sufficient detail to enable one skilled in the art to practice the invention once the patent expires. *Universal Oil Prods. Co. v. Globe Oil & Ref. Co.*, 322 U.S. 471, 484 (1944). Additionally, the disclosure informs the public of the precise scope of the monopoly asserted. *Id.*

Those functions of the patent disclosure show that experimental use of the invention during the patent term is inherent in the patent system. The public must be allowed to experiment with the invention in order to test the sufficiency of the patent disclosure. Otherwise, inventors could get patents without giving the public a complete disclosure of the invention. Similarly, advances in the art and im-

provements to the invention would be stimulated best by allowing experimentation during the term of the patent.

If experimentation is allowed, then, of course, companies or persons with a business intent should be allowed to experiment with the disclosure, because they would have the greatest motivation to test the patent. See Eisenburg, *Propriety Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 219-20 (1987).

The Court of Appeals for the Federal Circuit recently acknowledged the experimental use defense in *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). However, the *Roche* court's analysis of the experimental use defense, as a practical matter, virtually eliminates that defense. The *Roche* court improperly focused its analysis on whether the experimenter had any ultimate commercial objective, rather than on the character of the experimental use. The court stated that:

Unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention.

733 F.2d at 863.

The court incorrectly focused on the future commercial intent of the experimenter instead of on the effect the experimental use had on the patentee's lawful rewards. The error of that analysis is shown by its effect on the patent system. First, commercial entities, who undoubtedly have some future commercial motivation, would be foreclosed from testing the sufficiency of patent disclosures. Second, advances in technology would be stifled. Anyone with any

future commercial aspirations would not be allowed to experiment with a patented invention to improve it. Third, without the ability to experiment with the invention, businesses would be severely hampered in their ability to design around a patent. See *Yarway Corp. v. Eur-Control U.S.A., Inc.*, 775 F.2d 268, 277 (Fed. Cir. 1985) (“[T]he incentive to ‘design around’ patents is a positive result of the patent system.”).

Congress acted quickly in reversing the *Roche* court’s overly restrictive application of the experimental use defense by enacting section 271(e)(1). In doing so, Congress eliminated any precedential effect *Roche* may have had with respect to the experimental use defense.

[I]t simply makes no sense to apply *Roche* as precedent to nondrug products when the case has no precedential value as to the specific products of the *Roche* suit, namely, drugs. We can only conclude that Congress intended the enactment of section 271(e)(1) to set aside the *Roche* interpretation of section 271(a) in all of its ramifications.

Eli Lilly and Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir.), cert. granted, 110 S. Ct. 232 (1989) (opinion reprinted in Appendix to the Petition for Certiorari at page 1a).

C. The Experimental Use Defense To Infringement Under Section 271 Is The Counterpart Of The Experimental Use Doctrine Under 35 U.S.C. § 102

35 U.S.C. § 102(b) provides, in part, that a person is barred from getting a patent if “the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” 35 U.S.C. § 102(b). One of the policies underly-

ing the statutory bar of section 102(b) is “discouraging attempts to extend the length of the period of protection by not allowing the inventor to reap the benefits for more than one year prior to the filing of the application.” *T.P. Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 968 (Fed. Cir.), cert. denied, 469 U.S. 826 (1984). Stated differently, the intent of the on sale bar in section 102(b) “is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed.” *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983).

Although the language of section 102(b) would appear to prohibit any type of “public use” or “on sale” activity, the courts have construed that language as not including “experimental use.” In the seminal case establishing the experimental use doctrine, this Court stated, “The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [public use].” *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. (7 Otto) 126, 134 (1877).

If experimental activity by the patentee does not act to trigger the one year bar to obtaining a patent, it is logical that analogous experimentation by competitors should not be regarded as an enjoined act of infringement. That is particularly so in cases where the experimentation is intended to prepare a competing product for market after patent expiration.

1. 35 U.S.C. § 102(b) Is Designed To Prevent An Inventor From Encroaching Upon The Rights Of The Public

Experimental activities in the public arena prior to filing of a patent application are permitted because they are not viewed as an attempt to extract a longer patent term from the public. As this Court explained in *City of Elizabeth*:

It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended.

97 U.S. at 137.

The issue of whether there is a statutory bar to seeking a patent is determined by considering the circumstances surrounding the activity and weighing them against the underlying policies of section 102(b). *UMC Elecs. Co. v. United States*, 816 F.2d 647, 656 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1025 (1988). A sale of the invention does not necessarily negate the bar because, "[w]here, as incident to such [experimental use], the product of its operation is disposed of by sale, such profit from its use does not change its character; but where the use is mainly for the purposes of trade and profit, and the experiment is merely incidental to that, the principle, and not the incident, must give character to its use." *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 256 (1887). In other words, sales alone do not indicate that the inventor is trying to impair the rights of the public by extracting a longer patent term.

Similarly, aspirations of future profit also do not trigger the section 102(b) bar because "the mere desire to realize a profit sometime in the future in no way negates the inventor's intent to test his product in the present." *Preemption Devices, Inc. v. Minnesota Mining & Mfg. Co.*, 559 F. Supp. 1250, 1259 (E.D. Pa. 1983), *aff'd*, 732 F.2d 903 (Fed. Cir. 1984).

Other factors the courts have considered in determining whether the use was experimental include: (1) whether the inventor maintained control over the invention, *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987); and (2) whether the inventor told purchasers that the use was for experiments, *In re Dybel*, 524 F.2d 1393, 1401 (C.C.P.A. 1975).

2. The Public's Experimental Use Of A Patented Invention Should Be Allowed Just As The Inventor's Experimental Use Is Allowed

The experimental use defense to infringement is also like the experimental use doctrine under section 102(b) in that the defense helps to insure that the patent term is not extended beyond seventeen years. Nonpatentees must often experiment with making a patented invention to see if they can successfully utilize the invention. If experimentation is not allowed until after the patent expires, then the patentee enjoys a *de facto* patent extension during the period of experimentation by the public. The experimental use defense eliminates that extension.

The analysis for determining whether an activity is a noninfringing experimental use should be the same as the analysis for determining if a use is experimental under section 102(b). Both defenses are concerned with whether the activity is primarily experimental in nature or whether

the activity is mainly commercial in nature. Therefore, like the section 102(b) defense, the character of the noninfringing experimental use should not be destroyed merely because: (a) the experimental user has some future commercial aspirations; or (b) there have been sales which are incidental to the experimental use.

D. Medical Device Testing To Obtain FDA Approval Is An Experimental Use Which Does Not Deprive The Patentee Of His Lawful Rewards

1. The Preclinical Research Has No Commercial Effect On The Patentee

As discussed above, the preclinical investigation involves mechanical type testing and implantation of the device in animals. That investigation clearly does not affect the patentee's lawful rewards because: (1) no devices are sold; and (2) the devices are not implanted in people. Those activities simply cannot affect the patentee's commercial market. Therefore, the preclinical activities should be exempt from infringement liability as experimental uses of the invention.

2. The Purpose Of The Clinical Investigation Is To Obtain Scientific Data For Submission To The FDA And It Has A De Minimis Effect On The Patentee

The FDA's close regulation of the clinical investigation insures that the primary purpose of the investigation is to obtain scientific data. As discussed above, the manufacturer must obtain an Investigational Device Exemption ("IDE")

before conducting the clinical investigation. The policy for allowing IDE's is:

to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the development of useful devices intended for human use and to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. § 360j(g)(1). The FDA has described the purpose of clinical investigations as follows:

Clinical investigations of medical devices are conducted: *to gather information on device performance*, to determine if a new device is equivalent to a preamendments device, or to determine the safety and effectiveness of a device and *generate data* to justify premarket approval.

Food and Drug Administration, FDA Information Sheets, IRBS AND MEDICAL DEVICES (1989) (Emphasis added). Therefore, the clinical investigation is experimental in nature.

The regulations which implement the FDCA insure that the clinical investigational is not for commercial purposes. If the device is to be sold, an explanation must be given why the sales do not constitute commercialization of the device. 21 C.F.R. § 812.20(b)(8). The price for the device cannot be larger than that needed to recover the costs of manufacture, research, development, and handling. 21 C.F.R. § 812.7(b). Those sales are merely incidental to the clinical testing and are specifically considered noncommercial.

The regulations also insure that the manufacturer's clinical investigation will have a minimal impact on the patentee's commercial market. Before the investigation

begins, the manufacturer must submit an investigational plan which informs the FDA of the number of patients in the investigation and the duration of the investigation. 21 C.F.R. § 812.25. That plan cannot be changed without the approval of the FDA. 21 C.F.R. § 812.35. Also, the manufacturer is under a duty not to unduly prolong the investigation. 21 C.F.R. § 812.7.

The *de minimis* effect of the clinical investigation on the patentee's commercial market is illustrated by CII's replacement heart valve. Only 100-200 replacement valves are anticipated to be implanted into people. The annual market for heart valves in the United States is about 30,000-40,000. Therefore, the total number of heart valves that CII plans to implant is only about four-tenths of one percent of the heart valve market for a single year.

The factors which the court examined in *City of Elizabeth*, to determine that the activities were an experimental use which did not trigger a statutory bar also show that the clinical investigation is an experimental activity.

City of Elizabeth involved the experimental use of an invention relating to road paving. The paving was used to construct part of a toll road so that the inventor could test the qualities of the paving. 97 U.S. at 133. In holding that the experimental use doctrine applied, the court considered several factors. First, the court recognized that the nature of street pavement was such that it could only be satisfactorily experimented on if it was applied to a highway or road, which is necessarily public. *Id.* at 134-37. Second, the court noted that if durability was a concern, then the invention might have to be tested for several years to see if it satisfied its intended purpose. *Id.* In that regard, even if no changes were made during that period, the experimental purpose would not be negated. *Id.* A third factor was

whether the inventor maintained control over the invention. *Id.* Finally, the court noted that the public could derive a benefit from the experimental use.

Turning to clinical research of medical devices for FDA approval purposes, those factors are also present. First, as the FDA has recognized, a device, such as a heart valve, must be implanted into a human to determine its safety and effectiveness. Second, the device must remain in the body for an extended period of time to insure that the device will work properly. Medical devices often change and evolve during the course of the clinical investigation showing that the device is still in development even after it is implanted. J. Stein, *Manufacturers of Medical Devices Join the Chorus of Regulatory Critics*, Nat'l J. 1569 (Sept. 20, 1980). Third, the manufacturer is required to monitor the testing closely to ensure compliance with, among other things, the investigational plan and all applicable FDA regulations. 21 C.F.R. § 812.46. Finally, the patient is required to execute an informed consent before the device is tested on the patient. 21 C.F.R. § 50.25(a)(1). Therefore, the patient clearly knows that the use of the device is for experimental purposes. All of these factors point to excusing the clinical investigation as a noninfringing experimental use.

3. The Public Welfare Will Be Advanced By Allowing Testing For FDA Approval Purposes

The public welfare will be greatly advanced by allowing testing for FDA approval purposes during the patent term. Medical device technology is advancing at an ever increasing pace. Those advances will undoubtedly include improvements to a patented device. Without an experimental use defense, an improvement by someone other than the patentee could not be tested for FDA purposes until expiration of the seventeen year patent term. Instead of being

available to the public when the patent expired, the improvement would not be available until several years after the patent expired. Those years would be saved by allowing FDA testing during the patent term.

II. The Court Of Appeals' Construction Of 35 U.S.C. § 271(e)(1) Furthers The Goals Of The Constitution

CII believes that Congress obviated the need for medical device manufacturers to rely on the judicially recognized experimental use defense when it enacted 35 U.S.C. § 271(e)(1). Petitioner Lilly, however, asserts that section 271(e)(1) does not apply to medical devices. Lilly's construction is inconsistent with Congress' actions and the goals of the Constitution.

A. 35 U.S.C. §§ 156 and 271(e)(1) Were Enacted at the Same Time to Address the Problems Created By the Long FDA Approval Process

Congress recognized that the lengthy FDA approval process adversely affected both the patent rights of the inventor and the interests of the public. For the inventor, the approval process had effectively reduced the patentee's time for exclusive commercial exploitation of his invention. *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d at 405; Flannery and Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 270 (1985). One study had indicated that the process lasted seven to thirteen years for a pioneer prescription drug. *Id.* at 301. As discussed above, in the case of a heart valve, the approval period would likely be six to seven years. The seventeen year term that Congress had previously decided was needed to promote innovation was being diminished by

the FDA process. This diminution was shown, for example, in the erosion in pharmaceutical innovation. *Id.* at 302.

The lengthy approval process also impaired the public's ability to fully benefit from the patent disclosure at the end of the patent term. Two cases had established that a company could not undertake the FDA regulatory process until *after* any relevant patent had expired. *See Roche*, 733 F.2d 858; *Pfizer, Inc. v. International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982). Therefore, the FDA approval process effectively extended the patent term by the time required to gain FDA approval. Contrary to the scheme of the patent system, the public was denied the immediate benefit of the patent disclosure upon the patent's expiration.

Congress sought to correct the adverse effect of the FDA approval process on the patent system by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, which contained sections 271(e)(1) and 156. Section 156³ enables patentees to restore part of the patent term which was lost due to the lengthy FDA approval process for, among other things, medical devices. 35 U.S.C. § 156.

Section 271(e)(1)⁴ resolves the delay in getting the full benefit of the patent disclosure to the public by allowing one to "make use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." A company is allowed to complete the approval process during the term of the patent so that when the

³ Section 201 of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("DPC-PTR Act") added section 156 to title 35 of the U.S. Code.

⁴ Section 202 of the DPC-PTR Act added 35 U.S.C. § 271(e)(1)-(4).

patent expires that product can be offered to the public immediately.

Therefore, sections 271(e)(1) and 156 act in unison to reverse the detrimental effect the FDA regulatory requirements had on the patent system.

B. The Court Of Appeals Recognized That Section 271(e)(1) Must Apply To Medical Devices In View Of Section 156

The Court of Appeals recognized that sections 271(e)(1) and 156 were both enacted to address the adverse effects of the FDA regulatory requirements. *Eli Lilly*, 872 F.2d at 404-05. The Court of Appeals rejected Lilly's illogical argument that, in effect, asserted that Congress corrected those problems for drugs, but, with respect to medical devices, acted in favor of the patentee to the detriment of the public.

The patent term restoration provisions of section 156 indisputably apply to medical devices. *Id.* at 405. Therefore, if section 271(e)(1) only applies to drugs, as Lilly asserts, then a medical device patentee would not only be able to restore part of his patent term under section 156, he would also gain the effective patent term extension resulting from the FDA approval process. The patent term could effectively extend to twenty-nine years for a medical device (seventeen years for the patent grant plus seven years for the FDA approval process plus a maximum of five years under section 156). That conclusion implies that Congress decided to increase the patent term for medical devices with no concomitant benefit to the public. Such a result would be against the goals of the Constitution discussed above.

The ability of small medical device companies, such as CII, to develop and compete would be severely hampered

under Lilly's construction of section 271(e)(1). A new company would not be able to offer the public an improvement to a life saving invention until long after any relevant patent expired. Not only could this result deprive the public of the benefit of an improvement for an inordinate period, the delay would likely discourage the formation of new companies.

Lilly's construction of section 271(e)(1) would also put small companies at a competitive disadvantage to large companies like Lilly, and to foreign companies. Under Lilly's view, any testing of an improved medical device which might infringe an existing patent would have to be performed in a foreign country. Foreign companies, of course, could easily test their devices in their home country. Large companies with adequate financial resources could also test in a foreign country. However, most small companies would likely be unable to afford the exorbitant expense of transferring all of their operations to a foreign country. Therefore, small companies such as CII would have to wait six to seven years longer than larger companies, such as Lilly, and foreign companies to enter the market.

CII believes that these severe disadvantages to small start-up companies could be devastating. Not only would small companies find it difficult to compete, many small companies like CII might never be formed. The effect would be a decrease in innovation in the medical device industry because small companies have traditionally been a source of innovation in that industry. Office of Technology Assessment, Congress of the United States, *Federal Policies and the Medical Devices Industry* at 9, 17 (1984).

The court below recognized the error in Lilly's argument stating:

No persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation.

Eli Lilly, 872 F.2d at 406. That court's decision is in accord with this Court's admonition that "It is the duty . . . of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress." *Graham*, 383 U.S. at 688.

CONCLUSION

For the foregoing reasons, the decision by the Court of Appeals for the Federal Circuit should be affirmed.

Respectfully submitted,

MICHAEL M. PHILLIPS
*Counsel of Record
for Amicus Curiae*

515 N. Velasco St.
P.O. Box 1030
Angleton, Texas 77516
(409) 849-4382

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IN THE
Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
v. *Petitioner,*
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the
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LOUISIANA, MICHIGAN, MINNESOTA, NEVADA,
NORTH CAROLINA, RHODE ISLAND,
SOUTH CAROLINA, SOUTH DAKOTA, UTAH,
VERMONT, WASHINGTON AND WEST VIRGINIA
IN SUPPORT OF RESPONDENT

ERNEST D. PREATE, JR.
Attorney General
Commonwealth of Pennsylvania
(Counsel of Record)
Strawberry Square—16th Floor
Harrisburg, Pennsylvania 17120
(717) 787-3391

January 5, 1990

[Additional State Counsel Listed on Inside Cover]

Additional State Counsel

MARY SUE TERRY
Attorney General
Commonwealth of Virginia
101 N. 8th Street, 5th Floor
Richmond, Virginia 23219
(804) 786-2071

DON SIEGELMAN
Attorney General
State of Alabama
State House,
11 South Union Street
Montgomery, Alabama 36130
(205) 261-7300

JOHN STEVEN CLARK
Attorney General
State of Arkansas
200 Tower Building
Fourth and Center Streets
Little Rock, Arkansas 72201
(501) 682-2007

CHARLES M. OBERLY, III
Attorney General
State of Delaware
820 North French Street,
8th Floor
Wilmington, Delaware 19801
(302) 571-3838

WARREN PRICE, III
Attorney General
State of Hawaii
State Capitol, Room 405
Honolulu, Hawaii 96813
(808) 548-4740

NEIL F. HARTIGAN
Attorney General
State of Illinois
100 W. Randolph Street,
12th Floor
Chicago, Illinois 60601
(312) 814-3000

WILLIAM J. GUSTE, JR.
Attorney General
State of Louisiana
2-3-4 Loyola Building
New Orleans, Louisiana 70112
(504) 568-5575

FRANK J. KELLEY
Attorney General
State of Michigan
Law Building
Lansing, Michigan 48913
(517) 373-1110

BRIAN MCKAY
Attorney General
State of Nevada
Heroes Memorial Building
Capitol Complex
Carson City, Nevada 89710
(702) 687-4170

LACY H. THORBURG
Attorney General
State of North Carolina
Department of Justice
Two East Morgan Street
Raleigh, North Carolina 27602
(919) 733-3377

JAMES E. O'NEIL
Attorney General
State of Rhode Island
72 Pine Street
Providence, Rhode Island 02903
(401) 274-4400

T. TRAVIS MEDLOCK
Attorney General
State of South Carolina
Rembert Dennis Office Building
1000 Assembly Street
Columbia, South Carolina 29211
(803) 734-3970

ROGER A. TELLINGHUISEN
Attorney General
State of South Dakota
State Capitol Building
Pierre, South Dakota 57501
(605) 773-3215

R. PAUL VAN DAM
Attorney General
State of Utah
236 State Capitol
Salt Lake City, Utah 84114
(801) 538-1015

JEFFREY L. AMESTOY
Attorney General
State of Vermont
Pavilion Office Building
Montpelier, Vermont 05602
(802) 828-3171

KENNETH O. EIKENBERRY
Attorney General
State of Washington
Highways-Licenses Building
PB71
Olympia, Washington 98504
(206) 753-6200

ROGER W. TOMPKINS, II
Attorney General
State of West Virginia
State Capitol
Charleston, West Virginia 25305
(304) 348-2021

HUBERT H. HUMPHREY, III
Attorney General
State of Minnesota
102 State Capitol
St. Paul, Minnesota 55155
(612) 296-6196

*Attorneys for
Amici Curiae States*

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No. 89-243

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On Writ of Certiorari to the
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SOUTH CAROLINA, SOUTH DAKOTA, UTAH,
VERMONT, WASHINGTON AND WEST VIRGINIA
IN SUPPORT OF RESPONDENT

INTEREST OF AMICI CURIAE

The Commonwealths of Pennsylvania and Virginia and the States of Alabama, Arkansas, Delaware, Hawaii, Illinois, Louisiana, Michigan, Minnesota, Nevada, North Carolina, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Washington and West Virginia ("the States") file this brief as amici curiae in support of Re-

spondent Medtronic, Inc. ("Medtronic"). The States urge affirmance of the decision of the Court of Appeals for the Federal Circuit, which holds that under 35 U.S.C. § 271 (e) (1) it is not an act of patent infringement for a manufacturer to make and use a patented medical device solely to develop and submit information necessary to obtain regulatory approval to market the device. *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989). Affirmance of that decision is compelled by the express language of § 271(e) (1), which, as enacted in 1984, grants a patent infringement exemption for "the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." It also accords with the intent of Congress, that the statutory requirements for pre-marketing approval should not create a *de facto* extension of a patent holder's monopoly.

The interest of the States in this proceeding is to assure that their citizens have access to technological improvements in medical devices at the earliest possible time. Reversal of the Federal Circuit's decision would not only be contrary to both the unambiguous language of § 271(e) (1) and the Congressional intent, but would quite literally jeopardize the lives of countless persons by depriving them of advances in medical technology. For this reason, it is crucial that the balance struck by Congress and acknowledged by the Federal Circuit be preserved.

INTRODUCTION AND SUMMARY OF ARGUMENT

Resolution of the issue presented will have far-reaching effects on the delivery of health care in the United States. Only if the decision of the Federal Circuit is sustained will physicians, hospitals and patients have access to improved, state of the art medical devices immediately upon expiration of patents covering original devices. If the decision is reversed, patent holders will be granted a *de facto* extension of the patent term because competitors who make improvements upon the

original device will not be permitted to begin the testing required to obtain regulatory approval until expiration of the patent on the original device. The practical consequences of this Court's decision are vividly illustrated by the facts of the instant case.

Petitioner holds two patents related to implantable defibrillators, which are medical devices that automatically shock the heart to correct certain potentially fatal heart rhythms. As a consequence of the monopoly inherent in those patents, Petitioner's defibrillators currently are the only such devices commercially available in the United States. That monopoly will continue until at least October 26, 1990, the date on which the first patent expires. Should the Court accept Petitioner's argument, its monopoly would be extended for several more years because not until October 1990 would competitors be permitted to develop and commence the multi-year clinical testing necessary to obtain regulatory approval of a competing device.

Medtronic's device accused of infringement is a combination pacemaker, cardioverter and defibrillator. This combination device would make it possible for a single implant to treat multiple cardiac problems. By contrast, Petitioner's device does not have pacing capability. Thus, a patient who needs a defibrillator and a pacemaker must have two devices implanted. In the words of Petitioner's own expert, Medtronic's device could be the "ideal implantable device."

Medtronic has not yet marketed its device. It has begun to test the device and to gather data required under the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*). Such experimentation has been conducted under the authority of regulations issued by the Food and Drug Administration ("FDA"). If such testing is allowed to continue, Medtronic would be in a position to market its device shortly

after expiration of Petitioner's patent. On the other hand, if it is determined that such testing constitutes patent infringement, it may not resume until expiration of the original patent. In that case, the public would be deprived of this potentially "ideal" device for several years after expiration of the patent. More significantly, the same *de facto* extension would obtain with respect to countless other improved versions of patented medical devices. The cost in lives, prolonged suffering and consumer dollars would be enormous.

As we demonstrate below, it was precisely this result that Congress sought to prevent when it enacted § 271 (e) (1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Title II of that Act addresses the interplay of federal regulation of medical products and patent law in two ways. First, it permits the original patent holder to extend its patent term for up to five years to compensate for time (and hence profits) lost while awaiting FDA approval, which is required before a medical product may be sold in the United States. Petitioner has benefited from those provisions by obtaining a two-year extension of its original patent term. Second, it provides, in § 271(e) (1), that it shall not be an act of patent infringement to make and use a patented invention solely for the purpose of developing and submitting data under a federal law regulating drugs. Taken together, these provisions preserve the incentive for innovation and research created by the patent laws, while permitting "immediate competition" upon expiration of a patent term. See H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1 at 46 (1984). Petitioner's attempt to have the best of both worlds, an extended patent and a second *de facto* extension, should be rejected because it flies in the face of the express language of the statute and the policy objectives articulated in the legislative history.

I. The major, and we submit dispositive, point of difference between the States' position and that of Petitioner is as to the meaning of § 271(e) (1), if it is construed in accordance with an "ordinary reading" of its language. The key to resolution of the controversy is to ascertain the function of the word "drugs" in § 271(e) (1).

Section 271(e) (1) permits one to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates drugs." Thus, the word "drugs" sole function is to identify the class of regulatory federal laws which establish an approval process that involves the development of and submission of information concerning products. The word simply does not refer to, let alone limit, as Petitioner contends, the class of products which may be developed, or concerning which information may be submitted, within the protection of § 271(e) (1). Rather, the only requirement of the statute is that the use be reasonably related to the approval process "under a Federal law which regulates the manufacture, use, or sale of drugs." The FDCA clearly is such a law, and a submission with respect to "medical devices" is incontrovertibly a submission under that Act. 21 U.S.C. § 360. Since the language of § 271(e) (1) unqualifiedly exempts all submissions under that Act, there was no need for Congress to say anything more in order to include medical devices within its protection. See *United States v. Monsanto*, — U.S. —, 109 S.Ct. 2657, 2663 (1989).

Petitioner argues that the clause "a Federal law . . ." cannot refer to the *entire* FDCA because earlier in § 271(e) (1) Congress referred expressly to the "Federal Food, Drug, and Cosmetic Act," and it is contrary to accepted rules of construction to give the same meaning to different phrases in the same statute. The argument is specious because it disregards the true meaning of "a Federal law." That phrase clearly includes the FDCA, but it additionally refers to any other "Federal law

which regulates . . . drugs." Indeed, Congress' use of the indefinite article "a" strongly supports, if it does not compel, this meaning, and of course the FDCA is not the only such law. Thus, the two expressions which Congress used do have different meanings under the States' construction, and Petitioner's argument to the contrary is entirely baseless.

II. *Monsanto, supra*, also disposes of the Petitioner's contention that the committee reports explicitly state that "experimentation with a *patented drug product* . . . is not a patent infringement," (Pet. Br. 23; emphasis added by Petitioner), but do not specifically state that experimentation with a medical device is similarly protected. It is well established, however, that legislative references to the most obvious illustration cannot operate to limit broad statutory language to the specific examples referred to in the legislative history. 109 S.Ct. at 2662-63.

III. Petitioner contends that "sound policy considerations" favor its construction of the statute. Because none of the policy arguments advanced by Petitioner appears in the legislative history, they cannot be "attributed to Congress"; therefore, such considerations "cannot be determinative." *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980). The policy considerations which Congress actually articulated would be undermined by accepting Petitioner's view. The House Report said, in part, "[o]ther sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*" H.R. Rep. No. 98-857, Part 1 at 46. (Emphasis added.)

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION IS COMPELLED BY THE LANGUAGE OF § 271(e)(1)

Section 271(e)(1), as originally enacted, provided:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Pub.L. No. 98-417 § 202, 98 Stat. 1585 (1984) (emphasis added).¹

The States are in agreement with Petitioner that § 271(e)(1) should be construed in accordance with the "ordinary reading" of its language. Pet. Br. 14. We disagree, however, as to what that "ordinary reading" is. Petitioner contends that § 271(e)(1) creates a patent infringement exemption only for the development and submission of information concerning drug products. The States, in accord with the Court of Appeals, submit that § 271(e)(1) extends to information concerning any type of product, provided only that such information is

¹ The statute was amended in 1988 to read:

It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Pub. L. No. 100-670, 102 Stat. 3971 (1988).

developed and submitted under a federal law which regulates drugs. In section IA, we show that the construction suggested by Petitioner violates basic rules of grammar and reads a limitation into the statute that simply is not present. By contrast, as we show in section IB, the construction supported by the States is in accordance with the language of § 271(e)(1), which requires only that information be submitted under a federal law regulating drugs.

A. The Applicability Of § 271(e)(1) Does Not Depend On Whether Information Is Submitted Concerning A Drug Or Some Other Regulated Product

Petitioner's primary claim is that "[t]he ordinary reading of the . . . statutory language grants a narrow exemption from patent infringement for developing information necessary to obtain approval for 'drugs' and 'veterinary biological products', the specifically enumerated categories." Pet. Br. 14. Attention to the language and structure of § 271(e) reveals that this claim is untenable. Section 271(e)(1) permits one to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." Therefore, the word "drugs" is part of a prepositional phrase within the "which" clause that modifies "a Federal law." The word's sole function is to identify the class of regulatory federal laws which establish an approval process that involves the development and submission of information concerning products. The word "drugs" does not refer to, let alone limit, the class of products which may be developed, or concerning which information may be submitted within the protection of § 271(e).² Thus, Section 271(e) does not, as Petitioner

² The term "veterinary biological products," as added in 1988, further defines (by expanding) the class of laws to which § 271(e) relates. Thus, the contention at Pet. Br. 14, n.8, that "subsequent

asserts, apply only to "the development and submission of information concerning drugs." In short, Petitioner's reading of the statute is far from "ordinary;" it completely ignores the structure of the sentence and, most significantly, distorts the function of the word "drugs" on which Petitioner seizes.

Petitioner stresses the fact that the word "drugs" appears in § 271(e)(1), but the phrase "medical devices" does not. Pet. Br. 14. While that omission might have been significant if "drugs" defined a class of products to which § 271(e)(1) is limited, it is wholly irrelevant because, as shown above, § 271(e)(1) defines a class of laws and, as shown *infra*, the FDCA (under which Medtronic proceeded) is within that class of laws. So, too, since the word "drugs" in § 271(e)(1) does not have the function which Petitioner ascribes to it, it is entirely beside the point that the definition of "drugs" in the FDCA excludes medical devices. *Id.* Instead, the issue is whether the submission to FDA of experimental data concerning medical devices pursuant to the FDCA is made "under a Federal law which regulates . . . drugs." That critical proposition Petitioner unwittingly admits, for it continues: "Drugs and devices are regulated under entirely different statutory provisions. Compare 21 U.S.C. § 355 (drugs) with 21 U.S.C. § 360 (devices)." Pet. Br. 14-15, emphasis in original. Both provisions, 21 U.S.C. § 355 and 21 U.S.C. § 360, are part of the FDCA. See also Pet. Br. 15: ". . . the entire Federal Food, Drug, and Cosmetic Act, including the device provisions . . ." (emphasis in original). Thus, Petitioner admits (what could not in any event be controverted) that medical devices are regulated under that Act.

amendments confirm that Section 271(e)(1) is product specific . . .," merely repeats the error in the text of Petitioner's brief.

B. The Applicability Of § 271(e)(1) Does Depend On Whether The Information Is Submitted Under A Federal Law Regulating Drugs; The FDCA Is Such A Law

We next turn to what the States submit is the "ordinary reading" (Pet. Br. 14)—and indeed, the only fair and plausible meaning—of the language of § 271(e)(1). It will be convenient to set forth again the operative text as enacted in 1984:

It shall not be an act of infringement to make, use, or sell a patented invention * * * solely for uses reasonably *related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs* [emphasis added at Pet. Br. 14].³

This language does not exclude from its protection medical devices or any other products. It unambiguously and without limitation exempts from the prohibitions against infringement certain uses, *viz.* those reasonably related to the approval process ["the development and submission of information"] "under a Federal law which regulates the manufacture, use or sale of drugs."

The FDCA is unquestionably—and concededly (see p. 9, *supra*)—"a law which regulates drugs," and a submission pursuant to FDCA's device provision (21 U.S.C. § 360, cited at Pet. Br. 15) is clearly a submission under that Act. Since the language of § 271(e)(1) unqualifiedly exempts all submissions under that Act, there was no need for Congress to say anything more in order to include medical devices within its protection. An identical argument was rejected in *United States v. Monsanto*, — U.S. —, 109 S.Ct. 2657 (1989).⁴

³ The lengthy parenthetical expression which is omitted in the foregoing quotation is discussed at p. —, *infra*, in reply to Petitioner's reliance on a portion thereof.

⁴ In *Monsanto*, the respondent argued that the statute at issue was ambiguous because, although it provided that a person con-

Petitioner nonetheless contends that this "interpretation undeniably requires a strained reading of the plain language of the statute." Pet. Br. 15-16. This argument is based on an application of the guide to construction that, when Congress uses different terminology within a statute, it intends different meanings. We fully accept the principle, but as we now show, it is entirely consistent with our interpretation of the § 271(e)(1). We begin by setting forth Petitioner's argument.

Petitioner states: "To bring medical devices within the ambit of the statute, it is necessary to find that the phrase 'related to the development and submission of information under a Federal law, which regulates the manufacture, use, or sale of drugs, is shorthand for the entire Federal Food, Drug, and Cosmetic Act, *including the device provisions*, as well as the Biologics Act of 1902." Pet. Br. 15; emphasis in original. According to Petitioner, this cannot be because "a few lines earlier in Section 271(e)(1), Congress referred expressly to the 'Federal Food, Drug, and Cosmetic Act'; thus, it is argued that the Court of Appeals' (and the States') interpretation would 'giv[e], in effect, the same meaning to different phrases in the same statute.'" Pet. Br. 15-16. Therefore, argues Petitioner, "the term 'law which regulates . . . drugs' cannot 'mean the *entire* Federal Food, Drug and Cosmetic Act.'" Pet. Br. 16; emphasis added.

victed of certain offenses "shall forfeit * * * any property" derived from the commission of those crimes, it did not specify that "any property" included assets that could be used to pay the convict's attorney fees. This Court rejected that argument: "The fact that the forfeiture provision reaches assets that could be used to pay attorney's fees, even though it contains no express provisions to this effect, 'does not demonstrate ambiguity' in the statute: 'It demonstrates breadth.'" *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499, 105 S.Ct. 3275, 3286, 87 L.Ed.2d 346 (1985) (quoting *Haroco, Inc. v. American Nat. Bank & Trust Co. of Chicago*, 747 F.2d 384, 398 (CA7 1984))." 109 S.Ct. at 2662-63.

Petitioner's argument is entirely fallacious: Congress used different phraseology in the two passages to which Petitioner refers because it intended the first set of words to have a different meaning than the second set of words. Specifically, "Federal Food, Drug, and Cosmetic Act," refers to that statute alone; "a Federal law which regulates . . . drugs"⁵ means that statute *and* any other "Federal law which regulates . . . drugs." Indeed, Congress' use of the indefinite article "a" strongly indicates that Congress referred to and included more than one "Federal law." By contrast, Petitioner's reading of the phrase would include only certain sections (those relating to drugs) of a single law.

It is clear on the face of § 271(e)(1) that Congress recognized that the FDCA is not the only "Federal law" which regulates the manufacture, use or sale of drugs. If only "drugs" as defined in the FDCA were within the ambit of § 271(e)(1), there would have been no need to specifically exempt veterinary biological products "as defined in the Act of March 4, 1913."⁶

II. NOTHING IN THE LEGISLATIVE HISTORY PERMITS LIMITING THE SCOPE OF § 271(e)(1) IN THE TEETH OF ITS PLAIN LANGUAGE

Petitioner relies heavily on the fact that the committee reports explicitly state that "experimentation with a patented drug product . . . is not a patent infringement" (Pet. Br. 23, quoting H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1 at 45-46 (1984); emphasis added

⁵ It is revealing, perhaps, that at this point of its argument, Petitioner omitted the words "a Federal." Pet. Br. 16.

⁶ The "Virus-Serum-Toxin Act", Pub. L. No. 62-430, 37 Stat. 832 (1913) (codified as amended at 21 U.S.C. §§ 151-158). Additionally, Public Health Service Act of 1944, Pub. L. No. 78-410 § 351, 58 Stat. 682, 702 (1944) (codified as amended at 42 U.S.C. § 262) regulates the manufacture, use and sale of human biological products.

by Petitioner), but do not specifically state that experimentation with a medical device is similarly protected. It is well-established, however, that legislative references to the most obvious illustration cannot operate to limit broad statutory language to the specific examples referred to in the legislative history. *United States v. Monsanto*, 109 S.Ct. at 2662-63. *Accord Pittston Coal Group v. Sebben*, — U.S. —, 109 S.Ct. 414, 420-21 (1988) ("It is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.").

In *Monsanto*, the statute at issue (21 U.S.C. § 853) provided that a person convicted of certain offenses "shall forfeit . . . any property" derived from the commission of those crimes. In rejecting the argument that the statute could be construed to exclude from forfeiture assets that could be used to pay the convict's attorney fees, the Court first determined that, read literally, the statute covered *any* property. It then rejected the argument that the Court "should create such an exemption . . . because Congress simply did not consider the prospect that forfeiture would reach assets that could be used to pay for an attorney." 109 S.Ct. at 2662. The Court's reasoning on this point, which is likewise dispositive here, was as follows:

In support, respondent observes that the legislative history is "silent" on this question, and that the House and Senate debates fail to discuss this prospect. But this proves nothing: the legislative history and congressional debates are similarly silent on the use of forfeitable assets to pay stockbroker's fees, laundry bills, or country club memberships; no one could credibly argue that, as a result, assets to be used for these purposes are similarly exempt from the statute's definition of forfeitable property.

109 S.Ct. at 2662-63 (footnote omitted).

In the instant case, the statute is equally broad and unambiguous. Read literally, § 271(e)(1) covers submissions "under a Federal law which regulates . . . drugs." Congress' failure specifically to mention medical devices or other regulated products in the legislative history "does not lessen the force of the statute's plain language." *Id.* Nor is it surprising that the legislative remarks focus on drugs; after all drugs were the prototypical example considered in the case which Congress unquestionably sought to overrule, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984). In these circumstances, the legislative statements concerning drugs simply confirm the obvious—that submission of information concerning drugs is not patent infringement. "But none of these statements requires the negative inference" that similar submissions concerning medical devices, required by the same statute, do constitute patent infringement. See *United States v. Turkette*, 452 U.S. 576, 591 (1981).⁷

⁷ Petitioner's observation that "[c]ommentators on the 1984 legislation agreed that this provision 'is limited to human drug products, and does not include medical devices . . .'" (Pet. Br. 24, n.15) adds nothing to its case. The only commentary that makes such a statement is Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry; The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 Food Drug Cosm. L.J. 269, 308 (1985); the other commentary cited makes no such statement. Mr. Hutt represented the Pharmaceutical Manufacturers Association before Congress (see 40 Food Drug Cosm. L. at 269). This Court has held that "post-passage remarks of legislators, however explicit, cannot serve to change the legislative intent of Congress expressed before the Act's passage. . . . Such statements represent only the personal views of these legislators, since the statements were [made] after passage of the Act." *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 133 (1974) (emphasis added). *A fortiori*, post-enactment writings of partisans in the legislative process are essentially worthless. Moreover, the authors' conclusion is unsupported by analysis (or even reference) to the text of § 271(e)(1).

III. THE POLICY GOALS ARTICULATED BY PETITIONER ARE IRRELEVANT AND MISGUIDED, WHILE THOSE ARTICULATED BY CONGRESS FAVOR THE CONSTRUCTION ADOPTED BY THE COURT OF APPEALS

Petitioner contends at length that there are "sound policy considerations" favoring its construction of the statute. Pet. Br. 29-33. But since the language of the statute will not bear that construction, "this should [be] the end of the matter." Cf. Pet. Br. 15. Because none of the policy arguments advanced by Petitioner appear in the legislative history they cannot be "attributed to Congress"; therefore, such considerations "cannot be determinative," *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980). See Pet. Br. 29, n.14.

In any event, Petitioner's argument is unsound. Petitioner urges that because generic drugs can be approved under an abbreviated procedure which does not require clinical testing in patients with the underlying disease it has only a *de minimis* impact on the patent holder's right. Medical devices, however, must be tested in patients with the underlying disease; thus, "each patient who is treated with the investigational device is unavailable as a customer to the patent holder." Pet. Br. 30. Accordingly, Petitioner suggests that Congress could have concluded that § 271(e)(1) should not be extended to medical devices. *Id.* at 31.

The errors in this argument are twofold. First, § 271(e)(1) clearly permits testing of new drugs, as well as generic drugs. Like medical devices, new drugs require clinical testing in patients with the underlying disease and therefore deprive the patent holder of sales. Thus, while the differences noted by Petitioner might justify different treatment between generic drugs, on the one hand, and new drugs and medical devices, on the other hand, they provide no basis for distinguishing between

all drugs and medical devices, which is what Petitioner contends Congress did.

Second, as this case illustrates, clinical testing in patients has a *de minimis* impact on the patent holder. Medtronic's experimentation through the time of trial involved only 31 units having a total value of \$415,000. By contrast, Petitioner projects sales of 6,000 units during the term of its two-year patent extension. These sales will result in over \$100 million in revenue. Thus, considering only the final two years of the patent term, Petitioner will "lose" less than one-half of one percent in gross revenue as a result of Medtronic's clinical testing. The "loss" over the entire patent term will be infinitesimal, and will hardly discourage innovation as claimed by Petitioner.

Indeed, this case is illustrative of how the construction urged by Petitioner will discourage innovation. Although Medtronic's device is based upon Petitioner's original devices, it is a vast improvement in technology. See, *supra* at 3. Yet, if Petitioner's construction were accepted, this innovation would be unavailable to the public for several years after expiration of Petitioner's extended patent term.

While the policy arguments advanced by Petitioner are irrelevant and without merit, it is axiomatic that a statute should be interpreted, if possible consistent with its language, to accomplish the policy goals actually articulated by Congress. Cf., *Dawson Chemical Co.*, *supra*, 448 U.S. at 220-21. In the instant case, those policy goals are furthered by the construction given § 271(e)(1) by the Federal Circuit.

The policy animating § 271(e)(1) is explained in the House Report as follows:

Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should

be a definite time and, thereafter, immediate competition should be encouraged. For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product. Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. No. 98-857, Part 1 at 46. (Emphasis added).

If Petitioner's view is adopted "immediate competition" would be stifled, not encouraged, because the patent holder would obtain a *de facto* extension of the patent term in that marketing would have to await completion of clinical testing regulatory approval, which could not commence until expiration of the patent term. Moreover, the monopoly granted the patent holder would not be for a "definite time," but would vary depending upon the time required for competitors to obtain FDA approval of their new devices. Where the technology or the testing is relatively complex, the original patent holder might gain a monopoly of 22 years or more; where it is relatively simply, the monopoly might be closer to the 17 years granted by patent law.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

ERNEST D. PREAT, JR.
Attorney General
Commonwealth of Pennsylvania
(Counsel of Record)
Strawberry Square—16th Floor
Harrisburg, Pennsylvania 17120
(717) 787-3391

MARY SUE TERRY
Attorney General
Commonwealth of Virginia
101 N. 8th Street, 5th Floor
Richmond, Virginia 23219
(804) 786-2071

DON SIEGELMAN
Attorney General
State of Alabama
State House,
11 South Union Street
Montgomery, Alabama 36130
(205) 261-7300

JOHN STEVEN CLARK
Attorney General
State of Arkansas
200 Tower Building
Fourth and Center Streets
Little Rock, Arkansas 72201
(501) 682-2007

CHARLES M. OBERLY, III
Attorney General
State of Delaware
820 North French Street,
8th Floor
Wilmington, Delaware 19801
(302) 571-3838

WARREN PRICE, III
Attorney General
State of Hawaii
State Capitol, Room 405
Honolulu, Hawaii 96813
(808) 548-4740

NEIL F. HARTIGAN
Attorney General
State of Illinois
100 W. Randolph Street,
12th Floor
Chicago, Illinois 60601
(312) 814-3000

WILLIAM J. GUSTE, JR.
Attorney General
State of Louisiana
2-3-4 Loyola Building
New Orleans, Louisiana 70112
(504) 568-5575

FRANK J. KELLEY
Attorney General
State of Michigan
Law Building
Lansing, Michigan 48913
(517) 373-1110

BRIAN MCKAY
Attorney General
State of Nevada
Heroes Memorial Building
Capitol Complex
Carson City, Nevada 89710
(702) 687-4170

LACY H. THORNBURG
Attorney General
State of North Carolina
Department of Justice
Two East Morgan Street
Raleigh, North Carolina 27602
(919) 733-3377

JAMES E. O'NEIL
Attorney General
State of Rhode Island
72 Pine Street
Providence, Rhode Island 02903
(401) 274-4400

T. TRAVIS MEDLOCK
Attorney General
State of South Carolina
Rembert Dennis Office Building
1000 Assembly Street
Columbia, South Carolina 29211
(803) 734-3970

ROGER A. TELLINGHUISEN
Attorney General
State of South Dakota
State Capitol Building
Pierre, South Dakota 57501
(605) 773-3215

R. PAUL VAN DAM
Attorney General
State of Utah
236 State Capitol
Salt Lake City, Utah 84114
(801) 538-1015

JEFFREY L. AMESTOY
Attorney General
State of Vermont
Pavilion Office Building
Montpelier, Vermont 05602
(802) 828-3171

January 5, 1990

KENNETH O. EIKENBERRY
Attorney General
State of Washington
Highways-Licenses Building
PB71
Olympia, Washington 98504
(206) 753-6200

ROGER W. TOMPKINS, II
Attorney General
State of West Virginia
State Capitol
Charleston, West Virginia 25305
(304) 348-2021

HUBERT H. HUMPHREY, III
Attorney General
State of Minnesota
102 State Capitol
St. Paul, Minnesota 55155
(612) 296-6196

*Attorneys for
Amici Curiae States*

Supreme Court, U.S.

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No. 89 - 243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

v.

MEDTRONIC, INC.,

Respondent.

**On Writ Of Certiorari To The United States
Court Of Appeals For The Federal Circuit**

**BRIEF ON BEHALF OF
COOK GROUP INCORPORATED
AS AMICUS CURIAE IN SUPPORT OF
RESPONDENT MEDTRONIC, INC.**

CHARLES R. REEVES

Counsel of Record

WOODARD, EMHARDT, NAUGHTON,

MORIARTY & McNETT

One Indiana Square, Suite 2000

Indianapolis, Indiana 46204

(317) 634-3456

Counsel for Amicus Curiae

Cook Group Incorporated

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No. 89 - 243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,*Petitioner,*

v.

MEDTRONIC, INC.,

Respondent.

On Writ Of Certiorari To The United States
Court Of Appeals For The Federal Circuit

BRIEF ON BEHALF OF
COOK GROUP INCORPORATED
AS AMICUS CURIAE IN SUPPORT OF
RESPONDENT MEDTRONIC, INC.

INTEREST OF AMICUS CURIAE

Cook Group Incorporated is the parent and holding company for over thirty independent corporations (hereinafter collectively "Cook") involved in all aspects of the development, manufacture and marketing of medical devices. For over 26 years, Cook companies have been dedicated to the medical device business and to improving public health

and well being. Cook submits its brief in support of the Respondent Medtronic, Inc. ("Medtronic") in seeking affirmance of the decision below. Consent in writing was sought and obtained both from Medtronic and from the Petitioner Eli Lilly and Company ("Lilly") to the filing of Cook's brief. Copies of these consents are on file with the Clerk of this Court.

In explanation of its background and interest, Cook began as the dream of William A. Cook and his wife Gayle in 1963 to service the emerging field of percutaneous entry catheterization as a diagnostic means in lieu of the popular method of "exploratory surgery." Cook Incorporated was formed as a medical device manufacturer, and remains a major component in the Cook family of companies. Working principally with radiologists and cardiologists through the early years, it became apparent to Cook that other medical disciplines could also benefit from this technology and approach. Over time, Cook companies expanded into the fields of urology, gastroenterology, critical care and cardiac pacing. Cook companies were also added in the fields of plastic extrusions and moldings, stainless steel cannula manufacture and many support services.

Through this effort, Cook has emerged as a multinational group of independent, privately-owned companies intricately involved in the medical device business. Along the way, Cook spearheaded the work *inter alia* of Dr. Charles Dotter (once nominated for the Nobel prize in medicine for his work in this area) and funded many millions of dollars in private and public research including the recent establishment of The Charles Dotter Institute of Diagnostic and Interventional Radiology as an interdisciplinary medical facility at the University of Oregon. Cook has also been an active participant and supporter of patent systems, both U.S. and foreign, and has benefited both as

a patent owner and by learning from and improving upon the patented technology of others. As a result, Cook is a recognized leader in the creation and growth of interventional medicine in this Country.

In view of its past history and present status, Cook has a unique perspective from which to address the issues now before this Court. Cook has grown from a small family-run business to a significant medical device manufacturer, paralleling the growth and regulation of the medical industry by the Food and Drug Administration ("FDA"). Cook has a long working knowledge of the FDA, including routine if not daily contact regarding the thousands of devices Cook manufactures and markets. At the same time, Cook has remained independently and privately owned, retaining a family-run atmosphere divorced from shareholder and related pressures. This affords Cook a unique and different perspective on how a manufacturer of medical devices can influence the development of new products to improve the public health.

While Cook has monitored the progress of this case in the lower courts, Cook has now come forward for two important reasons: The first is to offer this Court Cook's unique perspective as suggested above. The second is to prevent this Court being misled by any suggestion of Lilly and its amici that all medical manufacturers abhor and detest the decision below. Quite the contrary, Cook is not only undisturbed by it, but applauds the Federal Circuit's decision. That decision does not curtail innovation of medical devices in this Country, but spurs on competition and earlier development and marketing of improvement products for the public well being. That decision does not rob the reward and hence the incentive from creativity, but returns opportunity to small companies often more innovative but unable to compete in off-shore clinical testing and

the like. That decision does not erode patent protection, but puts it back on course lessening any undue extension of the patent "monopoly" through increased FDA complexity and other regulation that often require years of testing and millions of dollars in investment. This dilemma, often referred to as the "regulatory patent", has worsened in recent years as large and small manufacturers alike have been increasingly hurt to the ultimate detriment of the public. *Roche v. Bolar* aggravated this situation, but Congress in enacting 35 U.S.C. § 271(e)(1) and the Federal Circuit's decision below are significant strides in the right direction.

Contrary to the views of Lilly and its amici, Cook supports Medtronic in requesting this Court to affirm the Federal Circuit's decision. In support of this position, Cook submits two alternative bases at law and persuasive policy considerations discussed below.

SUMMARY OF ARGUMENT

As its premise, Cook submits that testing of medical devices to meet FDA requirements is a permissible experimental use and therefore not an infringement of patents covering such devices. As such, the testing conduct comes within the judicially-created experimental use exception.

If in 1984 the Federal Circuit judicially removed both testing of drugs and testing of medical devices from the ambit of experimental use by its holding in *Roche v. Bolar*, then Congress has replaced both types of testing within the experimental use exception pursuant to its enactment of 35 U.S.C. § 271(e)(1), which was intended by Congress to overrule *Roche*.

If, on the other hand, the Federal Circuit's holding in *Roche* removed only the testing of drugs from the exception, then the testing of medical devices remains within the ambit of the judicially-created experimental use doctrine.

In either case, the testing of medical devices to meet FDA requirements is noninfringing experimental use—whether statutorily created by 35 U.S.C. § 271(e)(1) or judicially created by the experimental use doctrine. The Federal Circuit's decision was therefore correct at law and is supported by policy considerations as discussed below.

ARGUMENT

I.

The Experimental Use Exception Encompasses Conduct Which Does Not Deprive The Patentee Of The Lawful Rewards Of His Invention.

A. The Origins of the Experimental Use Exception.

The right of the patentee to exclude others from making, using or selling his patented invention has long been engrafted with the judicially-created exception that an experimental manufacture, use or sale is not an infringement. This exception spawned from language in two opinions authored by Justice Story of this Court. In *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), arguably in dicta, Justice Story stated that the legislature could never have intended, in enacting the then-existing patent statute, to punish one who manufactured an infringing machine for "philosophical experi-

ments" or "for the purpose of ascertaining the sufficiency of the machine to produce its described effects."

Several months later, Justice Story held in *Sawin v. Guild*, 21 F. Cas. 544 (C.C.D. Mass. 1813) (No. 12,391), that the experimental use exception he had discussed in *Whittemore* with respect to "making" a patented invention also applied to "selling" a patented invention. Just as "making" a patented invention is an infringement only if it deprives the patentee of the lawful rewards of his discovery, so too is "selling" a patented invention an infringement only if it deprives the patentee of the "use and benefit of his patent."¹ *Id.* at 555.

B. Later Cases Applying the Experimental Use Doctrine.

As in its inception, the experimental use exception to infringement has continued to be based upon the premise that a qualified manufacture, use or sale does not deprive the patentee of the *lawful* rewards of his patent. Several cases have applied that reasoning to conduct similar to that at issue here, and have found no infringement based

¹ Several commentators have suggested that the experimental use language in *Sawin v. Guild* was also dicta, although nonetheless supporting the doctrine's existence. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) And The Experimental Use Exception To Patent Infringement*, 16 Am. Intell. Prop. L.A.Q.J. 457, 459 (1989); Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. Pat. Off. Soc'y. 357, 364 (1957). However, in *Sawin* Justice Story was faced with conduct which came squarely within the words of the statute giving the exclusionary right of sale to the patentee. Even though the defendant deputy sheriff had seized the patentee plaintiff's machines under a writ of execution and sold the patented machine pursuant to the writ, Justice Story held the statute could not be interpreted to encompass his conduct. This holding was based, at least alternatively, on the fact that the sheriff had deprived the plaintiff only of material and not of the benefit of his patent.

upon the experimental use doctrine. *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (The court found that the government's use of a cobalt-nickel alloy for "testing and for experimental purposes" was not an infringing use.); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944), *aff'd on other grounds*, 156 F.2d 29 (2d Cir. 1946) (The court found one direction-finding, position-indicating system noninfringing because Lear built the system experimentally and neither manufactured it for sale, nor sold it.); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D. W. Va. 1937) (The court found Master Marble's use of a patented machine for making glass marbles was not an infringement but rather was experimental testing for a brief period before going into commercial production with a noninfringing machine, the marbles so made having not been commercially sold.)

While other courts have focused on the defendant's present commercial exploitation of the patented invention in refusing to apply the experimental use exception,² the

² Compare, *Bonsack Machine Co. v. Underwood*, 73 F. 206 (C.C. E.D.N.C. 1896) (contract with 60-day option to purchase infringing machine, *inter alia*, was not experimental use); *Cimiotti Unhairing Co. v. Derboklow*, 87 F. 997 (C.C.E.D.N.Y. 1898) (use of patented machine on customer pelts was not experimental); *Imperial Chemical Industries, PLC v. Henkel Corp.*, 545 F. Supp. 635 (D. Del. 1982) (supplying potential customers with samples of patented compound, *inter alia*, was not experimental use); *Poppenhusen v. New York Gutta Percha Comb Co.*, 19 F. Cas. 1048 (C.C. S.D.N.Y. 1861) (No. 12,279) (placing infringing articles in the market in competition with patent owner was not experimental); *Radio Corp. of America v. Andrea*, 15 F. Supp. 685 (E.D.N.Y. 1936) (quality control testing of commercial production was not experimental use); *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, 322 F.2d 34 (9th Cir. 1963) (use of patented method in commercial fishing operation was not experimental); and *United States Mitis Co. v. Carnegie Steel Co.*, 89 F.343 (W.D. Pa. 1898), *aff'd*, 90 F. 829 (C.C.A.Pa. 1898) (use of invention in the course of business and for profit was not experimental).

Chesterfield, Dugan and Akro cases stand for the proposition that even though the experimenter is in a business related to the patented invention and his activity has a definite view toward some future commercial adaptation or benefit, this is not determinative of infringement without concurrent actions to enter the relevant market or otherwise deprive the patent owner of his lawful rewards during the term of the patent.

II.

The Testing And Obtaining Of Government Approval For Medical Devices Does Not Deprive The Patentee Of The Lawful Rewards Of His Invention.

The patent statute grants to the patentee, his heirs or his assigns, the right to exclude others from making, using or selling the invention throughout the United States for the term of seventeen years. 35 U.S.C. § 154. This grant gives the patentee the "right to be free from competition in the practice of the invention," but only within the narrow and strictly confined limits of the precise terms of the grant. *Mercoind Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1941).

Clearly, Medtronic, Lilly and others who through R&D test and attempt to obtain government approval for future generic medical devices have an intention at some time after the expiration of any patents to commercially use and hopefully profit from what may presently be patented devices or other technology. So too is their intention to improve upon such available devices for the general public health and well being. This future intention to commercially exploit such medical devices at a time when they are part of the public domain in no way deprives the patentee of the lawful rewards of his invention.

The patent statute only grants seventeen, not seventeen *plus*, years of protection. The patentee is not entitled to freedom from competition based upon the patent statute after his patent has expired. *Brulotte v. Thys Co.*, 379 U.S. 29, 32-33 (1964) (If the patent exclusivity could be projected after the patent expires, "the free market visualized for the post-expiration period would be subject to monopoly influences that have no proper place there."); *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255-256 (1945) ("[A]ny attempted reservation or continuation in the patentee . . . of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent law."); and *Bonito Boats, Inc. v. Thunder Craft, Inc.*, 489 U.S. ___, 103 L.Ed. 2d 118, 135 (1989) ("It is self-evident that on expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property.") Nevertheless, the complexities of FDA and other regulatory requirements for medical devices can lead to this very result.

Congress has stated with respect to bioequivalency testing that such testing and obtaining of government approval does not have an adverse economic impact on the patentee's exclusivity during the 17-year life of his patent. H. R. Rep. No. 854, 98th Cong., 2d Sess. 46, reprinted in 1984 U.S. Code Cong. & Admin. News 2647, 2679. "The patent owner retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus the nature of the interference with the rights of the patent holder is not substantial." H. R. Rep. No. 854, 98th Cong., 2d Sess. 8, reprinted in 1984 U.S. Code Cong. & Admin. News 2686, 2692. This express reasoning is just as applicable to medical devices as to drugs. *Israelsen, supra*, at 464-65.

III.

The Federal Circuit In *Roche* Removed From The Experimental Use Exception All Experiments Conducted With A View To The Adaptation Of The Patented Invention To The Experimenter's Business.

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), the Federal Circuit examined for the first time the experimental use exception to patent infringement. The Federal Circuit recognized two important truths with respect to experimental use . . . first, that the scope of the term "use" in 35 U.S.C. § 271(a) has never been taken to its utmost scope; and second, that experimental use may be a defense to infringement. *Id.* at 861.

The Federal Circuit interpreted the experimental use exception very narrowly. The holding in *Roche* was that the defendant's use of a drug for testing and investigation related to FDA approval requirements was not an experimental noninfringing use because the use was made with a view to the adaptation of the patented drug to the defendant's business. *Id.* at 863. While outsiders may debate whether the Federal Circuit's removal of *all* such experiments from the ambit of the doctrine was by precedential holding or dicta, the Federal Circuit has itself recognized the breadth of its decision:

While the claimed subject matter in *Roche* was limited to a drug product, the holding of that case was not so limited. The holding provided an interpretation of the scope of 35 U.S.C. § 271(a) without regard to what particular goods might be involved. Specifically, the court decided that the unlicensed use of a patented invention for testing and investigation, even though strictly related to obtaining FDA approval for

a substitute, was an infringement under 35 U.S.C. § 271(a).

Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir.), *cert. granted*, 110 S. Ct. 232 (1989).

IV.

In Enacting 35 U.S.C. § 271(e)(1), Congress Intended Expressly Or Implicitly To Replace Within The Experimental Use Exception The Conduct Which The Federal Circuit Had Removed In *Roche*.

The uproar in the medical industry following *Roche* was loud, and Congress' remedy swift. Congress explicitly stated that the provisions of the Bill adding § 271(e)(1) "have the net effect of reversing the holding of the court in *Roche*." H. R. Rep. No. 854, 98th Cong., 2d Sess. 27, *reprinted in 1984 U.S. Code Cong. & Admin. News* 2647, 2711. The Federal Circuit itself recognized that Congress' addition of § 271(e)(1) to the patent statute "overruled *Roche*". *Eli Lilly & Co.*, *supra*, 872 F.2d at 405.

Thus, whether one interprets the holding in *Roche* broadly as did the Federal Circuit or narrowly as do Lilly and its amici, Congress intended to replace within the ambit of the experimental use exception to patent infringement whatever *Roche* by its holding had removed. With this understood, surely it can not be effectively argued that the underlying rationale of *Roche* in narrowly interpreting the experimental use doctrine has any remaining validity.

Extending this analysis, the testing of medical devices to secure FDA approval falls within the same umbrella justifying experimental use protection. If such testing was expressly removed from the experimental use doctrine by

the Federal Circuit's holding in *Roche*, it was replaced by Congress' enactment of 35 U.S.C. § 271(e)(1). If such testing was not removed by the holding in *Roche*, then it remains excused under the judicially-created experimental use doctrine and the discredited rationale in *Roche* should not be applied to overturn this result.

V.

Persuasive Policy Considerations Support This Court's Affirmance Of The Federal Circuit's Decision.

Thus far, Cook has addressed alternative bases at law to support this Court's affirmance of the Federal Circuit's decision either through interpretation of Congress' enactment of § 271(e)(1) or through interpretation of the judicially-created experimental use exception. There remains the need to comment on considerations of policy proposed by Lilly and its amici which Cook finds ill-conceived and possibly misleading of this Court.

For example, its detractors challenge the Federal Circuit's decision as significantly eroding and devaluing patent protection in medical devices. Certainly, this is not the case. Statutory and judicial safeguards are well in place to assure that preexpiration uses of a patented device are "experimental" and "... solely for uses reasonably related to the development and submission of information under a Federal law" 35 U.S.C. § 271(e)(1). It is wrong to assume the courts or the FDA or other regulatory agencies will fail in their duty to police potential abuses.

Moreover, equally-corrupt abuses existed in the past, and yet today, which are ameliorated by the decision below. FDA and other government regulations in the medical area have become increasingly complex over the years

resulting in *de facto* extensions of the patent term in what is often referred to as the "regulatory patent." The Federal Circuit's decision lessens the chance of such expansions of the patent "monopoly" occurring in the future to administratively create any superior class of patent owners.

Its detractors also challenge the Federal Circuit's decision as providing a significant adverse effect on medical device innovation and resulting disincentives for technology development and investment which otherwise benefit the public health and well being. Quite the contrary is true. A more expansive interpretation of the § 271(e)(1) exemption or the experimental use exception in fact opens up opportunities for the public and private sector to more rapidly and effectively assimilate new advancements in medical devices. Certainly, the advantages of independent access and verification by one's peers and the availability of prior invention to spur on future innovation are accepted scientific facts.

In the real world, as a patent nears its term, competitors assess the market for potential generic or substitute applications. So too do these competitors, and the patentee, assess the potential for improvement or spin-off utility of a patent throughout its life. If a new or generic medical device requires clinical testing, the manufacturer must not only reverse engineer the "clone" or its improvement, but in many instances must also obtain FDA marketing approval which at times can delay the introduction of such new or competing products for years. It could not have been the Framers' intent in our Constitution or Congress' intent in first enacting a patent statute or now with § 271 that all progress requiring use of a patented discovery for investigation or experiment should completely halt for the 17-year limited exclusivity

provided by law. On the contrary, the Constitutional mandate to "promote the progress of . . . the useful arts . . ." and statutory prescriptions ensuring early disclosure of inventions, including their adequate enablement and best modes, and acknowledging the availability of improvement patents certainly speak against any such conclusion. *Israel- sen, supra*, at 472.

Yet another misconception of these detractors is that the Federal Circuit's decision somehow unfairly prejudices the small manufacturer who does constitute a major segment of the medical device industry. Cook submits that the facts show otherwise. A review of recent acquisitions in this industry will demonstrate that small company innovation is still alive in this Country. This is true even with the disadvantage to small industry of the *Roche* holding and its rationale. Indicative of the current malaise is that major corporations prefer acquisition to internal development in many instances. Where this is not available, the ability of major industry to afford protracted regulatory procedures and off-shore clinical testing has severely prejudiced the small manufacturer in this industry.³ The Federal Circuit's decision brings small industry more at par with its larger relative. Under the decision below, the small manufacturer will now be encouraged to invest in verifying and improving upon its own innovation and that of others subject to the safeguards of § 271(e)(1) and the experimental use doctrine. As a result, the public

³ The public policy considerations in this Country against forcing or encouraging research and development technology overseas is above reproach. See *Israel- sen, supra*, at 475, note 86, citing, e.g., Cohen C., *Reagan Proposes a Bold Initiative*, Electronics 33 (August 6, 1987) (related to superconductors, in particular). Nevertheless, Lilly in its Petitioner's Brief to this Court at page 31, note 21, encourages Medtronic in this option.

will benefit from the encouragement of more rapid innovation and adaptation of existing discoveries.

Still another challenge to the decision below questions the Federal Circuit's special expertise in this area. In view of its unique history, however, the Federal Circuit is in fact the most appropriate forum short of this Court to have interpreted and applied patent policy in this Country in deciding the issues at hand.

CONCLUSION

As addressed above, support at law for the Federal Circuit's decision is found either in the § 271(e)(1) enactment or in the experimental use exception to patent infringement which was freed up by Congress' overruling of the earlier holding in *Roche*. More importantly, persuasive policy considerations support the Federal Circuit's decision and this Court's affirmance thereof. Accordingly, there being no clear error of law or public policy in the Federal Circuit's decision, it is requested that this Court decline the Petitioner's invitation to reverse and that this Court affirm the decision below in its entirety.

Respectfully submitted,

CHARLES R. REEVES
Counsel of Record
WOODARD, EMHARDT, NAUGHTON,
MORIARTY & MCNETT
One Indiana Square, Suite 2000
Indianapolis, Indiana 46204

Counsel for Amicus Curiae
Cook Group Incorporated

Date: January 5, 1990



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NO. 89-243

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V.

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Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
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**BRIEF OF AMICUS CURIAE
INTERMEDICS, INC.,
IN SUPPORT OF RESPONDENT**

John R. Merklings
Counsel of Record
INTERMEDICS, INC.
4000 Technology Drive
Angleton, Texas 77515
(409) 848-4196

OF COUNSEL:

Wayne E. Webb, Jr.
FULBRIGHT & JAWORSKI
600 Congress Avenue
2400 One American Center
Austin, Texas 78701
(512) 474-5201

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INTERMEDICS, INC.
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(409) 848-4196

OF COUNSEL:

Wayne E. Webb, Jr.
FULBRIGHT & JAWORSKI
600 Congress Avenue
2400 One American Center
Austin, Texas 78701
(512) 474-5201

QUESTION PRESENTED

Did the Court of Appeals for the Federal Circuit correctly construe 35 U.S.C. § 271(e)(1) to include an exemption for experimental use of medical devices?

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**BRIEF OF AMICUS CURIAE
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IN SUPPORT OF RESPONDENT**

INTERESTS OF THE AMICUS CURIAE

This Brief is filed with written consent of the parties in accordance with Rule 37.3. Intermedics, Inc. ("Intermedics"), a Texas corporation, is a manufacturer of medical devices including pacemakers, implantable defibrillators, implantable prosthetic joints, and heart valves. Intermedics is a subsidiary of Sulzer Brothers Limited, a Swiss corporation. As a

manufacturer of medical devices and holder of patents on medical devices, Intermedics is a competitor of both the Petitioner, Eli Lilly and Company ("Lilly"), and the Respondent, Medtronic, Inc. ("Medtronic").

The determination of whether or not an experimental use exemption for medical devices is provided under 35 U.S.C. § 271(e)(1) has a direct impact on the conduct of Intermedics' business. Intermedics, as the holder of numerous medical device patents, would benefit by a reversal of the Appellate Court. As a competitor with third parties holding medical device patents which is engaged in preliminary testing of experimental devices, Intermedics would benefit by an affirmation. Intermedics believes the Court of Appeals for the Federal Circuit correctly interpreted 35 U.S.C. § 271(e)(1) and therefore files this Brief in Support of that interpretation, siding with the Respondent, Medtronic, albeit for different reasons.

SUMMARY OF ARGUMENT

Although this case concerns the construction of the patent laws which inevitably calls into play arguments relating to public policy, Intermedics believes that construction of 35 U.S.C. § 271(e)(1) should be based strictly upon principles of statutory construction. A part of 35 U.S.C. § 271(e) was found by the Court of Appeals for the Federal Circuit to be ambiguous. The ambiguity, if any, should be resolved by reference to parallel, unambiguous parts of 35 U.S.C. §§ 156 and 271 to produce a harmonious, symmetrical result.

Both parties, and many of the Amici who have come forward to aid this Court, have taken the position that 35 U.S.C. § 271(e) is unambiguous on its face, or that any ambiguity may be clearly and unequivocally resolved by reference to the legislative history. The Court of Appeals for the Federal Circuit did not agree. Although there are many aspects of this legislation that are clear, it was not clear to the Court of Appeals for the Federal Circuit whether an FDA experimental use exception to

infringement was extended to medical devices. Under these circumstances, a court should look for guidance to the actions of Congress in adopting the unambiguous, parallel portions of the statute and seek, as nearly as possible, to follow the pattern established thereby.

Sections 156 and 271(e)(1) unambiguously provided an extension of the patent term for drugs subject to regulatory delay (§ 156) and a corresponding experimental use exception (§ 271(e)(1)) for FDA testing of drugs. This legislation overruled the only relevant precedent, *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir., 1984). Section 156 of the statute clearly provided an extension of patent term for medical devices, but it was not clear to the Court of Appeals for the Federal Circuit whether Section 271(e)(1) provided a corresponding FDA experimental use exception for medical devices. To resolve this perceived ambiguity, the Federal Circuit correctly followed the pattern set by Congress, and abandoned its own precedent in its entirety, finding it nonsensical to retain the *Roche* holding as precedent for all non-drug products.

Intermedics requests this Court to affirm the statutory construction of the Court of Appeals for the Federal Circuit which recognized the propriety of reconciling facially ambiguous statutory provisions to produce a harmonious, symmetrical result which is consistent with legislative intent.

ARGUMENT

I. The Scope of 35 U.S.C. § 271(e) is Unclear.

This is a case where the appellate court found the exact meaning of a statute to be unclear, and construed the statute in light of legislative intent. It has been argued by the parties and by numerous Amici that the statute "plainly" and "clearly" requires opposite results. Each side has argued that both the statute and its legislative history support their respective positions. The parties and various Amici have also argued that the possible effects of different interpretations on industry,

innovation and the public support their respective views. This Amicus adopts *in arguendo* that the appellate court correctly concluded that the statute is ambiguous. It cannot be said that medical devices are clearly and unequivocally included or excluded from the scope of 35 U.S.C. § 271(e).

Nevertheless, because a case has been brought to the courts for adjudication, the courts must adopt one interpretation or the other. This is the function of the courts, and it is not judicial legislation, although it will shape the law. To choose one interpretation is as much of an exercise of the judicial role as to choose the other. The choice, however, should be made on principles which can be reliably followed in other similar cases.

II. In Interpreting the Statute, the Court Should be Guided by the Action of Congress.

Congress speaks most clearly through its actions. It is impossible for a court or a litigant to poll a legislature, long after it has dissolved, for its interpretation of the meaning of a statute. Statements by individual legislators are of little assistance, for the opinions and sentiments of one cannot reasonably be attributed to all. To the extent a legislature has a unified intent, it is expressed in the action of the majority in adopting particular legislation, coupled with the corresponding action of the executive branch. To interpret statutes, a court should direct its attention, as much as possible, to the action of Congress in the unambiguous, parallel portions of the legislation. That is precisely what the Court of Appeals for the Federal Circuit has done in this case.

35 U.S.C. § 271(e)(1) was enacted in response to the decision by the Court of Appeals for the Federal Circuit in *Roche*. In that case, the Federal Circuit was asked to find that preliminary FDA testing was within the judicially created experimental use exemption from infringement. The Federal Circuit refused to do so. Later, Congress overruled the *Roche*

decision. On its facts, therefore, *Roche* has no further precedential value.

In overruling *Roche*, Congress clearly created an FDA experimental use exception for drugs under 35 U.S.C. § 271(e). At the same time, Congress provided an extension of the patent term for drugs which became 35 U.S.C. § 156. This is the undisputed, unambiguous action of Congress, an action which abolished the precedential value of *Roche*. In 35 U.S.C. § 156, Congress also unequivocally extended the patent term for medical devices. The scope of 35 U.S.C. § 271(e), which unequivocally provided the experimental use exception for drugs, does not clearly include or exclude medical devices, and the Court must provide an interpretation.

The methodology for interpretation adopted by the Federal Circuit offers the greatest potential for predictability and precision in the interpretation of statutes. The Federal Circuit turned back to the statute itself, perceived that Congress, in return for an FDA experimental use exception, had granted drug manufacturers a patent term extension and that Congress had granted device manufacturers a patent term extension but may or may not have imposed, in return, an FDA experimental use exception. The Federal Circuit resolved the ambiguity it found by treating the action of Congress in the handling of drugs as the best evidence available for the interpretation of the statute. Under the Federal Circuit's interpretation, drugs and devices are treated in the same way. Such an interpretation harmonizes the two sections regarding the treatment of patented inventions subject to regulatory delays, is consistent with congressional intent to overrule the *Roche* decision and is a proper exercise of judicial authority in statutory interpretation. *Federal Power Commission v. Panhandle Eastern Pipe Line Company*, 337 U.S. 498, 514; 69 S. Ct. 1251, 1260 (1949). This interpretation also results in consistent interpretation of the term "patented invention" throughout 35 U.S.C. § 271.

CONCLUSION

The Court of Appeals for the Federal Circuit correctly resolved the ambiguities in 35 U.S.C. § 271(e) so that the parallel portions of the statute would be consistent. The Federal Circuit's principled application of a doctrine of statutory interpretation should be affirmed.

Respectfully submitted,

John R. Merkling
Counsel of Record
INTERMEDICS, INC.
4000 Technology Drive
Angleton, Texas 77515
(409) 848-4196

OF COUNSEL:

Wayne E. Webb, Jr.
FULBRIGHT & JAWORSKI
600 Congress Avenue
2400 One American Center
Austin, Texas 78701
(512) 474-5201